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July/Aug 1977 AEI Journal on Government and Society

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Regulation

July/Aug 1977 AEI Journal on Government and Society

Competition of ideas is fundamental to a free society

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About This Journal

This journal is a response to the extraordinary growth in the scope and detail of government regulation. Surely this phenomenon is one of the two or three most significant political facts of our times. Yet, because the extension of regulation is piecemeal, the sources and targets diverse, the language complex and often opaque, and the volume overwhelming, much of this activity escapes public notice and therefore public debate. Partly in consequence, old regulatory agencies and programs remain and new ones are frequently launched with little analysis of the problems being addressed, of costs and possible side effects, and of alternative methods for achieving the same ends.

While there are specialized periodicals that discuss a thousand other subjects, there is no journal devoted to examining the policy implications of the regulations that affect our public and private endeavors and to discussing this subject in a readable style. *Regulation* is designed to fill that gap.

We define our subject broadly to include regulatory activity of all kinds—legislative, judicial, and administrative—whether directed at economic, political, social, or cultural affairs. The immediate purpose is to provide information and analysis about specific issues. The longer-range purpose is to foster an analytical approach to regulation, so that policy choices in this area will proceed in fuller awareness of the available options and the consequences for American society as a whole.

In seeking authoritativeness and diversity, we shall draw upon a wide community of academicians and experts, including the scholars and fellows of the American Enterprise Institute. The judgments reflected in the articles we print, in the analytical notes in "Perspectives," and in the summaries in "Readings" are, of course, those of the contributing scholars and editors, not of AEI, its officers, or advisory panels.

The editors of this journal recognize that, in a complex industrial society, a substantial measure of regulation may be necessary. We are committed, nonetheless, to the ideal that this regulation should be sensible, cost-efficient, and as unburdensome as the nature of its objectives will allow. In the coming years, we hope to advance that ideal by stimulating informed public discussion.

Anne Brunsdale

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Perspectives
on current developments

Issues in Airline Regulatory Reform

For the first time since the creation of the Civil Aeronautics Board in 1938, federal economic regulation of the airline industry is under sustained attack. In October 1975 President Ford sent Congress a proposal to allow more entry into the airline business, to give carriers more discretion to set fares and abandon unprofitable markets, and to limit the CAB's power to grant antitrust immunity for carriers to collude over rates and services. Earlier, in February 1975, Senator Edward Kennedy's Subcommittee on Administrative Practice and Procedure had issued a report strongly favoring liberalization of CAB regulation. On March 4 of this year, President Carter, in a special message to Congress, endorsed a reduction in federal regulation of the airlines. And in March and April, the Senate and House aviation subcommittees held hearings on the subject.

Dozens of government and nongovernment studies have shown that CAB regulation produces economic inefficiency. The fares charged by the intrastate airlines in California and Texas are traditionally 30 to 50 percent lower than CAB-regulated fares for comparable distances. Though in some ways consumers benefit from the nonprice competition that results from CAB regulation, the value of those benefits is shown in these studies to be less than the increase in fares. Estimates of the net costs of regulation, which vary considerably, range into the billions of dollars per year.

Opponents of airline regulatory reform argue that it would eliminate scheduled service to many small communities, bankrupt numerous large air carriers, and cause substantial unemployment for airline labor. Two volumes being published by the American Enterprise Institute—*Regulatory Reform*, edited by Thomas Gale Moore and Robert A. Nesser, and *Regulation of Passenger Fares and Competition among the Airlines*, edited by Paul W. MacAvoy and John W. Snow—disagree. Both point out that evidence from the unregulated commuter airlines and intrastate carriers suggests that a reduction in regulation would eventually lead to better service for small communities. In any case, the proposed reforms include provisions to ensure the continuation of service to small communities. Papers in these volumes also argue against the specter of carrier bankruptcy: The lower fares that would result should stimulate demand, so that the load factors would rise. The increased demand would, moreover, require an increase in the number of employees in the passenger service areas. Thus, though the rate of growth in air crews and other personnel supporting flights might not rise as rapidly as it has, the rate of growth in ticket agents, reservations personnel, and baggage handlers should be significantly higher than in the past.

Two approaches to airline regulatory reform are under consideration by the Congress, neither of which amounts to complete deregulation. A bill sponsored by Senators Howard Cannon and Edward Kennedy (S.689) would give the CAB a timetable for initiating specific reforms and would set limits on the extent to which the board could restrain competition. A bill sponsored by Senators James Pearson and Howard Baker (S.292)—and supported by the CAB—is more open-ended, for it would give the board general guidelines for reform but allow it considerable latitude as to how to go about achieving reform—and indeed as to how much reform will be achieved. Working under a similar discretionary plan for reforming regulation of the railroads, the Interstate Commerce Commission has come up with findings that are basically anticompetitive and consistent with the kinds of regulation it has promulgated in the past.

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On Cable-TV and "Lobbying" before the Agencies

In a March 25 decision, the U.S. Court of Appeals for the District of Columbia struck down several regulations of the Federal Communications Commission restricting cable TV, the most important of which prevented subscription cable systems from competing with broadcast TV for rights to some feature films and sporting events (*Home Box Office, Inc.* v. *FCC*, 1977). The decision is a major victory for cable in the "siphoning" controversy—which involves two issues: will "free," advertiser-sponsored TV deteriorate in quality if pay-cable is permitted to bid freely for the most desirable programming, and, if so, does the FCC have authority to prevent this? Of much greater government-wide importance, the decision imposes a new prohibition against informal, off-the-record contacts with all regulatory agencies in rulemaking proceedings.

1. Of course, the most critical issue in the siphoning dispute is whether, given deleterious effects upon "free" TV, the FCC has authority to prevent competition for programming. The court does not conclude this issue. It finds that the commission relied upon inadequate grounds of authority, but suggests that it would support FCC intervention (given a proper factual showing of harm) if only the commission would base its action upon statutory authority to regulate the content of entertainment programming. In an earlier decision (*Citizens Committee to Save WEFM* v. *FCC*, 1974), the present court found that such authority exists, but the FCC has obstinately refused to use it, persisting in what the present opinion disapprovingly calls "the *laissez faire* approach."

The siphoning ruling rests, for the most part, on evidentiary grounds. The court held that the FCC had not produced sufficient facts to show that the public interest requires the preservation of "free" broadcasting as the basic national service. The latter point involves the long-standing contentions of broadcasting advocates that the quality of the present system must be preserved (1) because much of the nation can never be "wired" since the costs would be prohibitive in some places (rural and inner-city areas) and (2) because the poor would not be able to pay for cable programs. The cable industry's replies include the assertions that fiber-optics will dramatically reduce wiring costs in the next decade; that new technology will soon enable rural areas to be served by direct-broadcast satellites instead of local stations; that "free," advertiser-sponsored programs will exist in the wired nation as well; and that if the poor need special assistance it should be given directly, rather than through suppressing a new technology.

It seems clear that when enough households are "wired," cable will be able to outbid advertiser-sponsored TV for certain programs. Advertiser sponsorship means that only the *breadth* of a program's audience appeal, not its *intensity*, can be effectively turned into a profit—since the advertiser pays on the basis of estimated total audience, no matter how ardent the enthusiasm of the audience may be. Pay TV, on the other hand, by charging a high fee for a program that is intensely popular, can capitalize upon the depth as well as the breadth of appeal. This has the advantage of making commercially feasible the sort of programming that attracts a limited but highly enthusiastic audience. Thus the Metropolitan Opera might be televised to a relatively small audience at a relatively high fee. But it also means that programs which are *both* widely *and* intensely popular and which are now shown on "free" TV (for example, the World Series) will be more lucrative to cable entrepreneurs, who might charge, let us say, 50 cents per viewer, than to commercial broadcasters, who are only able to exact a few cents per viewer from advertisers. The issue which the present court finds not resolved on the basis of the evidence adduced in the FCC rulemaking is whether such siphoning will occur to a degree that affects the overall caliber of "free" TV.

2. In the last portion of its opinion, the court found the FCC proceeding to be invalidated by "ex parte contacts" (roughly equivalent to off-the-record discussions of the issues) between persons outside the agency and FCC commissioners and staff. Such contacts have not hitherto been thought unlawful in rulemaking proceedings, unless there are special agency-imposed restrictions. The new prohibition will have a far-reaching impact upon rulemaking throughout the federal government. Some of its probable effects will be (1) to reduce substantially the voice of the regulated

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industry in rulemaking, particularly in one-industry agencies such as the FCC where staff and the commissioners have frequent informal contacts with industry representatives; (2) to reduce the influence of the congressional committees with substantive jurisdiction over the agencies, whose chairmen and members are often consulted (or volunteer their views) informally; (3) to increase substantially the power of agency staff members who draft proposed rules, since they alone among all the participants in the proceedings will have informal access to the decision-makers; (4) to impede, to some extent, agency acquisition of the expertise that comes from constant informal discussion with the regulated industry —since even the most generalized issues (for instance, in the present case, the anticipated growth rate of cable) may be relevant to a pending rulemaking and thus not a proper subject of discussion; and (5) to cause agencies to examine proposed rules more carefully *before* issuing them for comment (since it is only upon issuance that the ex parte prohibition attaches), with the result that the task of persuading a regulatory commission to change a proposed rule will be harder than it is now.

An extraordinary eight weeks after the original opinion was issued, one member of the panel expressed some second thoughts on the ex parte prohibition. In a separate concurring opinion published on May 20, Judge George MacKinnon stated his intent to limit that prohibition to rulemakings that "involve competing private claims to a valuable privilege or selective treatment of competing business interests of great monetary value." Since Judge MacKinnon's views on this point are in a minority, the categorical sweep of the ex parte prohibition remains the court's decision.

3. The FCC has acquiesced in that portion of the decision which eliminates restrictions upon the purchase of feature films, but is seeking Supreme Court review of the remainder. Because of the far-reaching importance of the ex parte point, it seems likely that the Supreme Court will accept review. Thus, the *Home Box Office* decision may give the Court an occasion to reexamine its earlier decisions concerning the scope of FCC jurisdiction over cable TV. That jurisdiction is only derivative, arising from the fact that cable systems (in addition to originating programming) acquire and transmit to their viewers the broadcast-TV signals that are the FCC's primary field of jurisdiction. In its *Midwest Video* decision (1972), the Court upheld the FCC's power, on the basis of this derivative jurisdiction, to compel cable systems to originate programming (instead of merely retransmitting broadcast signals). The decision was five to four. One of the five, Chief Justice Burger, wrote a separate concurrence, in which he acknowledged that the commission's action "strains the outer limits" of its jurisdiction, and suggested "the need of a comprehensive reexamination of the statutory scheme as it relates to [cable], so that the basic policies are considered by Congress and not left entirely to the commission and the courts." It is a real possibility that the Supreme Court will be willing to reach the issue which the court of appeals in the present case avoided: the authority of the FCC to protect "free" TV against competition from cable in the program market.

Improved UHF Reception— How Much? Who Will Pay?

Purchasers of new television sets may have to pay a premium for improved UHF reception whether they want improved reception or not. They will, if the Federal Communications Commission approves a proposed change in regulation sought by the CUB (Council for UHF Broadcasting) and others.

The CUB contends that (1) the All-Channel Receiver Act of 1962 requires that reception through UHF and VHF be comparable and that (2) since UHF reception tends to be inferior to that of its rival, "whatever can reasonably be done to improve UHF is *per se* in the public interest and should be undertaken absent a strong showing of detriment to the public." The UHF broadcasters want the FCC to require TV manufacturers to upgrade UHF tuners by lowering the permissible noise level (the "snow" in the picture) from eighteen decibels to ten over a thirty-month period. This standard could be met, they claim, with present technology at a relatively low cost.

In response, the Consumer Electronics Group, which represents all major American manufacturers of TV sets and several Japanese

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companies with plants in the United States, argues that the CUB is pushing for standards that exceed the capabilities of present technology. What is more, the CEG argues, even if the standards were feasible, meeting them would be far more costly than the CUB alleges and would increase the chances of cross-channel interference. These points the CUB denies.

Comparability can be achieved, of course, in other ways. The alternative preferred by the manufacturers would be to require UHF broadcasters to increase their transmitting power. Reception would then be improved for all UHF viewers, not just those with new sets. The CUB claims that stronger signals would cause "overlapping" among neighboring stations and would be prohibitively expensive for most UHF stations.

Clearly, self-interest is involved on both sides. While both groups would gain from improved UHF reception, the manufacturers (and their customers) would bear the cost of the CUB proposal, while the broadcasters (plus their viewer/contributors or their advertisers) would bear most of the cost of the CEG alternative.

Another way to get comparability would be to spread the cost by finding an appropriate combination of increased transmitting power and higher tuner standards. Milton Kafoglis of the Council on Wage and Price Stability, working with existing data, analyzed alternative combinations for reaching a nine-decibel improvement. He concluded that it would cost roughly $300 million to achieve the first six-decibel improvement through better tuners, compared to only $80 million through increased power; for the remaining three decibels, however, better tuners would cost only $150 million, compared to over $190 million for increased power. This implies that the least-cost means of achieving comparability is through a combination of tuner improvement and increased broadcasting power. Whether such an approach will be adopted depends on the outcome of further research and on the FCC's decision.

Also at issue in this case is whether the All-Channel Receiver Act requires comparability, as the CUB asserts. This issue may have to be resolved in the courts.

OSHA and Work-Place Hazards: Cotton Dust

Only in the last few years has cotton dust come to be regarded as a major health hazard. OSHA, responding to a recommendation from the National Institute for Occupational Safety and Health, proposed last December to tighten its standard for worker exposure to cotton dust from 1.0 milligram per cubic meter of air to 0.2 milligram.

Workers exposed to the cotton dust found in most phases of textile manufacture have an above average propensity to develop respiratory ailments, particularly byssinosis (or brown lung, a condition associated only with cotton dust). In order to reduce the level of exposure, the Occupational Safety and Health Administration proposes "engineering controls"—that is, the installation of machinery to clear the air. Until these controls are installed, respirators would be required, and they would remain in use in those areas where the standard could not be met exclusively through reliance upon engineering controls.

The economic impact statement accompanying the proposed standard raises important questions. First, though the cost of the required equipment is carefully worked out—$2.7 billion in capital investment and $261.6 million in yearly operating costs, for an annualized cost of $694.9 million—the attempt to estimate benefits is decidedly weak. There is little quantification of the overall impact of byssinosis—for example, its mortality rate and the extent to which it is disabling—and no discussion of possible cures. OSHA's analysis only provides a rough partial estimate of how many cases of byssinosis would be avoided by moving from the present standard to the proposed standard—388 cases a year in yarn production and 1,361 in weaving.

Second, there is reason to wonder if OSHA's proposed standard is the least costly way to reach the objective of reducing disease and loss of life. In other words, is the proposal cost-effective?

- The data given in the economic impact statement indicate that the average cost of avoiding a case of byssinosis would be $388,000. This figure is higher than some agencies budget to avoid *deaths*—not illnesses—sug-

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gesting that more deaths might be avoided if the resources were put, instead, into areas like highway safety or cancer research.

- The standard is to apply uniformly across the industry, even though the estimated annual *marginal* cost per illness avoided is $632,000 for yarn production and $1.22 million for weaving. This spread implies that a tighter standard for yarn production and a looser standard for weaving could achieve the same reduction in illness at a much lower cost.
- The economic impact statement reveals, and then ignores, an enormous difference between the costs of "personal protection devices" (in this case, individual respirators) and the costs of engineering controls. The figures point to annual savings from respirators of about $222 million—or $1,721 for each of the 129,000 workers exposed. Perhaps workers would be willing to wear respirators if some of the savings were passed along to them.
- The analysis does not discuss the possibility that medical surveillance and revised work practices might deal with the problem at a lower cost than the proposed approach. By itself, byssinosis is not fatal—and, if detected soon enough, is reversible. A program of mandatory medical exams and worker rotation seems to be an option worth considering.

Third, the proposal does not sufficiently explore the effect that costs of the magnitude contemplated in OSHA's proposal would have on the entire textile industry. Because of imports and synthetic fibers, there is not much room in this industry for price increases to accommodate large increases in cost. Since rates of return are extremely low as it is, little of the cost increase could come out of short-run profits. Thus textile manufacturers could be expected to clamor for greater protection from foreign imports, and some manufacturers could be expected to have to reduce wages or cut back on production, or both.

Trouble for White-Water Rafting?

Recent interpretations of coastwise trading laws, if enforced, will produce expense for both white-water outfitters and those who enjoy the sport. In a ruling last year, the U.S. Coast Guard held that portions of many of the treacherous rivers used for rafting are "navigable." Thereupon the U.S. Customs Service determined that the Jones Act, which requires that all commercial vessels on U.S. navigable waters be constructed in the United States, applies to white-water rafts.

Unfortunately for the tiny industry that thrives on introducing novices to the thrill of shooting rapids, large numbers of the white-water rafts used come from Europe. These rafts supply a large—and apparently growing—share of the market. *Business Week* has estimated that about 60 percent of the rafts used today are imported. Zodiac of North America, Inc., a distribution subsidiary of a major foreign producer, puts imports at some 80 percent of all recently purchased rafts. Generally speaking, Europe makes the small rafts, roughly thirteen to seventeen feet long, whereas the United States makes the "grandaddies," which are up to forty feet long. Most of these large rafts are government surplus relics from World War II that have passed from owner to owner, been patched and repaired, but never cast aside.

The Jones Act, a collection of laws regulating U.S. coastwise trade, was enacted in 1920 to protect the U.S. maritime industry from foreign competition. It seems far-fetched on the face of it to think that this purpose is served by applying the act to white-water rafts. Moreover, foreign rafts do not appear to be threatening American jobs and firms, and apparently nobody has sought to bar them from the market. Most domestic producers build their large rafts as a minor sideline of their basic businesses (generally tire manufacturing), and the bulk of their production is still for the military. They seem content to leave the small raft market largely to foreign producers—whose products, incidentally, tend to be of higher quality than the closest domestic equivalents and cost up to 20 percent more.

Whereas the benefits of "protection" would be negligible, the costs would be significant. There would be shortages of the smaller rafts until prices rose sufficiently to encourage domestic production. Meanwhile, there would be disappointed customers and losses for the outfitters who rely heavily on foreign equipment. In the end customers would pay more for what they would be getting. Furthermore, the protectionist intent of the Jones Act would

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eventually be circumvented as foreign manufacturers opened factories in America, which Zodiac already intends to do. The upshot might be a clamor for special taxes on these foreign-owned U.S.-based operations to "protect" the expanding domestic industry.

Gerald Jantscher observed in his study of the maritime industry (*Bread upon the Waters*, Brookings, 1975) that the least obvious, seemingly least important instances of government intervention often provide the best illustrations of regulatory costs. The application of the Jones Act of 1920 to a sport that can hardly be called maritime points out the hazards of blindly applying old regulations to new situations.

Import Restrictions on Sugar, Shoes, and TV Sets

Responding to petitions from domestic producers of sugar, shoes, and TV sets, the International Trade Commission recommended in February and March that President Carter approve import limitations to protect domestic industry. Strongly supporting the ITC's action were domestic manufacturers and organized labor. Opposed, because import limitations would mean increased prices, were some organized consumer groups.

Under the Trade Expansion Act of 1962, workers or firms suffering substantial injury because of reductions in trade barriers could apply to the Department of Labor or the Department of Commerce for adjustment assistance. Since the criteria for demonstrating injury were high, not much assistance was granted under this act. In the Trade Act of 1974, Congress liberalized those criteria. It authorized the ITC (formerly the U.S. Tariff Commission) to recommend governmental relief for any firm or labor group able to demonstrate the threat of serious injury from imports, and it scrapped the requirement that the injury be caused by reductions in trade barriers. Relief can take the form of adjustment assistance, tariffs, quotas, or some combination of the three.

In early 1976, President Ford rejected an ITC recommendation for import relief for domestic shoe manufacturers and their employees, stating that the cost to consumers did not justify such action. Later that year, the ITC reopened the question. In hearings, manufacturers and labor union representatives called attention to dramatic reductions in domestic production and employment, and a number of congressmen and senators from shoe-producing states testified on their behalf. Finding for the petitioners, the ITC recommended that President Carter impose a 40 percent tariff on shoe imports exceeding 265 million pairs annually (the present tariff ranges between 6 and 15 percent). When the domestic television and sugar industries petitioned the ITC for similar relief, the commission recommended an additional tariff of 20 percent on foreign television sets (the current tariff is 5 percent) and a quota of roughly 4.3 million tons on imports of sugar, syrups, and molasses (the current quota is 7 million tons).

President Carter rejected the ITC's recommendations. In April, he directed Special Trade Representative Robert Strauss to negotiate "voluntary" agreements to reduce exports of shoes and TV sets to the United States. In May, he announced that he would grant domestic sugar producers "deficiency payments" of up to 2.0 cents per ton when the market price fell below 13.5 cents per ton. Later in May, Mr. Strauss announced that Japan had voluntarily agreed to limit its exports of TV sets to 1.75 million a year, compared with 2.96 million during 1976.

A key problem with import restrictions is that the value of the aid to domestic producers is less than the increased costs borne by consumers. Under a quota system, domestic producers receive a higher price for their product, as do the importers fortunate enough to fall within the quota. Under tariffs, domestic producers receive a higher price, but the importers' potential higher returns are given over to the U.S. Treasury. Generally, economists favor relief in the form of adjustment assistance since, in theory at least, it does not have significant efficiency costs: commodities are obtained from the cheapest source, domestic or foreign, and manufacturers and workers are helped to adjust to the results of changes in the comparative advantage between domestic and foreign production of those commodities.

These concepts are illustrated in testimony given before the ITC by two economists of the

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Council on Wage and Price Stability. John F. Morrall estimated that a 20 percent tariff on shoes (only half the tariff proposed by the ITC) would cost consumers about $2.4 billion a year. Of this, $1.85 billion would be received by the shoe industry, $400 million would be collected as tariff revenue and $150 million—representing the amount consumers not in the market would be willing to pay for the option of purchasing shoes at the lower price—would constitute a "dead weight loss to society." The number of jobs saved would be about 8,500, and the cost of saving a job would be about $18,000 per year. With respect to TV sets, Morrall maintained that the cost of saving one job through an additional tariff of 10 percent (again only half the ITC's recommended level) would be about $17,000 a year.

Thomas Lenard, in his testimony, estimated the annual results of a 4 million ton sugar quota as follows: the benefits to domestic and foreign producers would range between $57.6 million and $323 million; the increased cost to consumers and the reduction in U.S. government tariff receipts would be between $63.5 million and $333.8 million; and the net cost to society (that is, the excess of total cost over total benefits) would be between $5.9 million and $10.8 million.

Voluntary export agreements—President Carter's solution for shoes and TV sets—have the same overall effect as a quota: consumer costs are higher than the aid given to domestic producers and their employees. In addition, they permit returns to be reaped by those controlling the exports to the United States—presumably the foreign governments with whom the agreements are reached. Not surprisingly, foreign governments usually prefer this approach to tariffs or quotas.

The major alternative to import restriction, adjustment assistance, is opposed by management and organized labor. Both would naturally prefer to have their positions guaranteed than be assisted into other positions. Nevertheless, their criticism has merit. While the number of claims certified for assistance has risen dramatically under the Trade Act of 1974, processing the claims takes so long that most of the assistance goes to firms and individuals who have already reestablished themselves in other businesses and other jobs. Even with rapid processing, moreover, adjustment assistance would still work as a disincentive by impeding the adjustment process. This has led some to suggest changing the program so as to grant lump-sum payments at the initial stage of the transition, and to allow market forces to speed the adjustment process. This approach would appear to meet the equity concerns over firm and employee dislocation, while being more efficient than the existing program of adjustment assistance—and far more efficient than import restraints.

Containing Hospital Costs

The Carter administration is developing a new program of government regulation in an effort to slow the rapid rise in health care costs. The first step is the proposed Hospital Cost Containment Act of 1977, which would limit revenue increases for acute-care hospitals to approximately 9 percent in the first year and place a national ceiling on capital expenditures by these hospitals. The next step, now promised for 1978, would be more extensive controls as part of a national health insurance plan.

The cost of an average hospital stay increased by 15 percent in 1976 and, if not restrained, is expected by many to do the same in 1977. Currently the largest share of health care expenditures—40 percent—is for hospital care. By slowing the projected increase in hospital revenues to 9 percent, the Carter administration expects net public and private savings of $1.9 billion in the program's first year.

A limit on annual revenue increases would force hospitals to economize on the services they offer. This feature of the plan represents a form of controls less restrictive than outright wage and price controls, but restrictive nonetheless. Except for the wages of nonsupervisory personnel, a hospital would not be able to use higher costs to justify increases in revenue beyond the 9 percent cap. The exception could be significant: with only labor costs being passed through, the use of labor might increase in some areas, while at the least the incentives to keep labor costs down would be weak.

A national ceiling on capital expenditures would add a new *federal* layer of controls to existing restraints on expenditures for hospi-

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tal expansion or improvement. The ceiling, expected to be set at about half the $5 billion spent for this purpose in 1976, would be distributed among the states according to population factors, construction costs, and the need for expansion or modernization. The states would ration their quotas to hospitals through federally required certificate-of-need programs.

In short, the plan—if enacted—would subject a major segment of the health care industry to a system of controls that strongly resembles public utility regulation. Controls on capital expenditures would be administered by local health systems agencies, controls on revenue increases through existing third-party payers (Medicare, Medicaid, Blue Cross, state agencies, and private insurers). The Carter administration expects that, by using these review mechanisms, only a small federal bureaucracy would be needed to run the program.

The proposal is, at best, a partial or quick-fix nostrum for the problem it is designed to remedy. There are three main causes of rising hospital costs: (1) the use of retrospective reimbursement, (2) the costs of keeping up with rapid advances in medical technology, and (3) the third-party reimbursement system. The hospital cost containment bill addresses the first and the second, but not the third—which is generally considered the most important. In the case of the first—the fact that payment comes after services have been performed and is based on their cost, so that hospitals have little incentive to economize—the proposed limits on revenue increases would lead hospital managements to find ways to limit their costs. In the case of the second—the costs associated with new technology—the proposed ceiling on capital expenditures would strengthen existing arrangements designed to keep hospitals from buying equipment that will be underutilized and whose purpose is mainly to attract medical staff.

For the third major cause—the problems introduced by third-party payment—the bill would do nothing. About 90 percent of all hospital bills are now paid through public and private insurance. When patients pay little or none of their hospital bill directly, they tend to accept more expensive services where cheaper would do—for example, in-patient care where out-patient treatment would be equally appropriate. Third-party payment has grown, among other reasons, because rising incomes have given families and individuals more money to spend for health insurance premiums. Also, income tax laws that allow individuals to deduct their health insurance premiums and businesses to deduct the cost of the health benefits they provide have made nontaxed health benefits more valuable (at some income levels) than equal amounts of taxable income. Finally, the federal programs of Medicare and Medicaid, which now account for 60 percent of the federal health budget, include restrictions that encourage the use of expensive hospital services at times when nursing homes, out-patient clinics, and home health care would do.

In addition to the fact that the bill does not deal with third-party payments, there is a subsidiary difficulty. Many metropolitan hospitals, whose out-patient services often provide the only medical care available to poor and needy big-city residents, might have to cut back some of these money-losing services.

Government health programs and tax laws have been the major forces behind rising hospital costs, and these costs, in turn, have made the programs more expensive and created political pressures to solve the problem. Rather than adjusting the incentives in its programs and tax laws to induce more cost-conscious behavior, the government's response is to apply a regulatory tourniquet. Experience with revenue control regulation in other industries has been that, in the long run, it leads to more comprehensive controls and creates vested interests that can be expected to resist changes in technology, regulation, or consumer preferences.

Saccharin and the Public Interest

Of all the regulatory bombshells of recent years, few have burst so noisily as the Food and Drug Administration's proposal of April 15 to ban most uses of saccharin. The action followed Canadian tests showing that massive doses of saccharin led to bladder tumors in rats. Given this evidence, the FDA had no choice. The Food, Drug, and Cosmetic Act and, more particularly, its 1958 Delaney amendment, compel the agency to prohibit food additives that cause cancer in humans or animals

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(that is, are carcinogenic), however remote the risk for humans and however great the offsetting benefits. This exacting standard does not apply to drugs—which the FDA is permitted to judge on a risk/benefit basis.

On June 17, after two months of public debate focusing largely on the relevance of animal tests results for humans, the FDA claimed support for its proposal from a new Canadian study. This one surveyed 480 men and 152 women with bladder cancer and found a higher incidence in men who use saccharin than in men who do not. As we go to press, bills are moving through Congress to delay the ban so that the evidence may be more fully evaluated.

Americans use over 6 million pounds of saccharin a year, roughly one-tenth of this in the form of pills and table-top sweeteners and the balance as an additive in foods, beverages, and nonfood products (such as lipstick, toothpaste, and drugs taken orally). The FDA's proposed regulation would ban all use of saccharin as an additive. It would, however, permit its reclassification as a single-ingredient over-the-counter drug—thus making it available in pill form and for table use—*if* and when the manufacturer demonstrates its effectiveness for medical uses. (Meanwhile, saccharin could be sold over the counter in containers displaying cancer warnings.) Observers doubt the manufacturer will be successful, because saccharin's only benefit is that it is a sugar-free sweetener. This is a kind of efficacy not previously acceptable as grounds for approving a new drug.

Views about the proposed ban turn on interpretations of the data, assessment of costs and benefits, and the matter of free choice.

(1) On the Canadian animal tests, critics claim the results are irrelevant for humans, since a person would have to drink 800 diet sodas a day to match the saccharin intake of the test animals. In reply, FDA scientists and others argue that such doses are a valid way to determine carcinogenicity in a short period, and insist that a significant incidence of cancer in test animals strongly implies some incidence in humans after normal long-term use.

On the new Canadian survey, critics question its finding of a link between saccharin and cancer and cite similar surveys by the American Health Foundation and by researchers at Johns Hopkins that found no such link.

(2) Projections of the incidence of cancer that would be avoided by the ban vary widely: the Office of Technology Assessment, a congressional agency whose report called saccharin a "weak" carcinogen, estimates that 15 to 15,000 cases would be avoided annually, while the FDA *now* (after the new Canadian survey) puts the maximum at 2,400. (Both estimates assume a lifetime consumption of one diet drink per day by 200 million people.)

The estimated costs of the ban are less uncertain. The FDA's economic impact statement shows lost sales of saccharin products running from $607 million to $2 billion annually, depending on public response to "low-calorie" natural sweeteners, how fast industry can adjust its production to these sweeteners, and the rapidity with which current stocks of saccharin products are depleted. Use of sugar instead of saccharin in human and animal foods would raise the annual costs of these foods by $98 million and $10 million respectively, until an equivalent chemical substitute for saccharin is found. (The only plausible candidate, Aspartame, is still several years away from approval.) The Council on Wage and Price Stability says these figures are low—by roughly $144 to $182 million—because they put no value on what consumers would pay, above market price, to have an artificial sweetener.

There are other, less measurable costs. For example, without saccharin, many medicines that are taken orally could not be made palatable, because sugar is either not sweet enough to do the job or incompatible with the active ingredients. In the view of the Pharmaceutical Manufacturers Association, a saccharin ban would "create a serious health hazard" for children. There is also concern about the effects of unsweetened toothpaste upon dental hygiene. Finally, a ban would make it more difficult for the obese and the diabetic to stay on a regimen of sugar control. This cost, alone of those that would be imposed by the FDA's action, would be eased if saccharin could be reclassified as an over-the-counter drug.

(3) Six witnesses testifying for OTA split evenly on the proposed ban. The three opponents advised that consumers be allowed to decide for themselves whether the benefits of saccharin were worth the risks. Given the Delaney amendment, this route is not open to the FDA.

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Opinion

A Regulated Society? *Irving Kristol*

No reasonable person is *in principle* opposed to all government regulation. None of us wants to coat our walls with a paint that slowly poisons the air we breathe, just as none of us wants our kids to wear pajamas that have been treated with a carcinogenic chemical. It is true that, in theory, a free market can cope with problems such as these. The manufacturers of lead-free paint or Tris-free pajamas should simply be able to take the market away from the others. But this involves creating and disseminating to the entire population an enormous amount of accurate information (some of it highly technical) about a vast range of products—information, moreover, which changes rapidly. There really is no efficient way to achieve this. It is absurd to expect consumers to become experts in such matters, when most of them have neither the capability nor the time. They can compare prices easily enough, and can roughly compare the quality of competing items—but when "quality" involves fairly arcane scientific knowledge, the communications system represented by a free market breaks down, so far as the ordinary person is concerned.

It is for this reason that all nations regulate their medical professions at least to the degree of certifying who is a doctor and who is not. The assumption behind such regulation is that the consumer is in no position to make the certification decision for himself—as most of us know and freely admit. And it is for this same reason that the drug companies would be the first to oppose the idea that drugs should go completely unregulated. They fear, quite properly, that such havoc would be wreaked as to result, in the end, in a state-owned monopoly to protect the consumer against his own vulnerable ignorance.

So there is no argument about regulation in principle, and the polar distinction between the regulation of commercial transactions and the free market, so often heard, is not very meaningful in practice. Moreover, it is reasonable to expect that in a more densely populated society, consuming an ever-greater variety of technically sophisticated goods, there would be more regulation rather than less. People will want greater protection against their own incapacities as consumers. They will also, of course, want protection from the side effects (the "externalities") of other people's activities as producers, which now are observed to affect them to an ever-increasing degree. Such observations themselves are often the result of more sophisticated scientific inquiry, which uncovers externalities we were not previously aware of.

But the same complexities that give rise to more government regulation also make effective regulation a very difficult enterprise. The hard questions are: what kind of approach should be used, where, and to what degree—questions that merit sober, informed, and prudent judgment. And one may wonder: can such judgments be made by people who are eager, as many among us are, to use the regulatory mechanism as a lever for transforming the social and economic order as a whole? I have in mind the people—the "New Class" as they have come to be called—who do not, on balance, like a free, commercial society: that is, a society shaped by voluntary commercial transactions among consenting adults, in short, one whose central economic institution is the marketplace. They sincerely believe that a powerful government, in which they have positions of authority, can order things better. If one designates them, in a

Irving Kristol is a resident scholar at the American Enterprise Institute and chairman of the Advisory Council of AEI's Center for the Study of Government Regulation. He is also co-editor of the quarterly The Public Interest *and a member of the* Wall Street Journal*'s Board of Contributors.*

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short-hand way, as "Naderites," one would not be far off the mark.

I must be careful here, because I do not want to be understood as suggesting some nefarious, secret conspiracy to transform the American social and economic system. There is no such conspiracy—in large measure because there is no need for one. When we create a vast regulatory apparatus, with goals sanctioned by law and public opinion, we have also created a whole set of power centers to which people of the New Class naturally gravitate.

And here we must be candid as well as careful. Though officialdom will deny it—sometimes naively, sometimes not—it is a fact that most of those holding career jobs in EPA, OSHA, and other newer regulatory agencies have an ideological animus against the private economic sector.* This is a fact evident to anyone who has had any dealings with them, or who has ever had the opportunity to meet with them socially. They are not in those jobs because they could not find any others. Most of them, in truth, are sufficiently educated and intelligent to find better-paying jobs in the world of business. But they are not much interested in money. They are idealistic—that is, they are concerned with exercising power so as to create "a better world."

It is interesting to note that there is one subject toward which these intelligent people, with an above-normal intellectual curiosity, show a positive distaste—and that is the subject of economics. Ask them to contemplate the economic implications of their regulatory actions—in the form of economic impact statements, say—and they exude a cold hostility. Why? One explanation, frequently heard, is that they are merely displaying a bureaucratic distortion of vision. Having been given the mission of regulating, they resent the intrusion of any *modus operandi* that will distract them from doing this one thing that defines their role. This explanation is unsatisfactory. These "bureaucrats," far from being bureaucratically myopic, are full of opinions on many matters, and are really not much concerned about their futures in the bureaucracy or even about the future of the bureaucracy itself.

No, the plain fact is that these are people who are discontented—often in a vague and unfocused fashion—with modern technological civilization, and especially with the economic system that they see as the progenitor of this civilization. They are inclined to believe that a "planned" economic system would create a superior way of life for all Americans. They detest the individualism so characteristic of a free society, which is why they will speak so favorably of "mass transit" and "planned communities" and so contemptuously of the private automobile and "suburban sprawl." They also, therefore, have little use for private economic enterprise, and are utterly indifferent to the costs they load upon it.

Some critics have called these regulators elitist. The accusation never hits home because the members of this New Class are absolutely convinced that they are protecting "the people" against the iniquities of "the system." A better term might be "liberal paternalists," understanding "liberal" to mean something like what "social democratic" means in Europe.

But however labeled and defined, they are incontestably there, wielding an immense power that Congress is reluctant to check or balance. After all, what congressman wants to be publicly excoriated by a host of "experts" for spreading cancer among his constituents? In any case, the staffs of many congressmen—and of many congressional committees—are composed of these same people of the New Class.

Sooner or later, however, checks and balances will have to be provided, if we are not to slide into a regulated society, one in which the scope for individual decision-making (in our personal lives as well as in business) is increasingly narrowed. A vast net of paternalistic protectionism, cast over all of our activities, will lead to economic, social, and political tensions of the most grievous kind. Americans want reasonable regulation, but it is highly unlikely that they are so risk-averse as to wish to be protected against all possible risks, particularly if it means a radical dilution of their powers of self-government. We have never been that kind of people and it is hard to believe that our national character has changed so drastically over these past fifteen years.

* The older regulatory agencies (the ICC, CAB, and so on) are in a different category altogether. They were born out of fear of monopoly, not a distrust of business enterprise per se. They have no ideological animus against business—though they tend to stifle competition, for fear of its leading eventually to monopoly.

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Lessons of the Economic Impact Statement Program

James C. Miller III

ADDRESSING the Congress in October 1974, President Ford announced that he would require government agencies to assess the inflationary impact of their major proposed regulations and legislative recommendations. A month later he established, by executive order, an Inflation Impact Statement (IIS) Program that was to run through 1976 and apply to all executive branch agencies. At the end of 1976, Ford extended the program and changed its title to the more descriptively accurate Economic Impact Statement (EIS) Program. (In the interests of simplicity, this title and acronym will be used here, with the caveat that they should not be confused with those of the Environmental Impact Statement Program.)

Because of strong opposition from organized labor—owing especially to claims that the EIS requirement delayed regulations at the Occupational Safety and Health Administration (OSHA)—many thought that President Carter would terminate the program. Instead, he has given it strong support, most recently on April 15, when he announced several measures dealing with inflation. Specifically, he asked that full consideration be given to "the economic cost of major government regulations, through a more effective analysis of their economic impact," and directed the Council on Wage and Price Stability (CWPS) "to provide relevant agencies with analyses of the inflation implications of specific government regulatory and legislative actions."

Meanwhile, support for the EIS initiative has been growing in Congress, where there is considerable interest in strengthening the program and applying it to the independent regulatory agencies as well as those within the executive branch. Bills have been introduced to require all agencies to prepare "regulatory cost/benefit assessments" of their proposed legislation and regulations having a significant economic impact (H.R. 351 and H.R. 701); to have the Congressional Budget Office prepare economic impact statements for proposed legislation and agency regulations (H.R. 1743); and to require agencies to prepare economic impact statements for proposed regulations, submit them to CWPS for comments thirty days in advance of their appearance in the *Federal Register*, and publish the analysis and CWPS's comments along with the proposed regulation (H.R. 2100).

In view of President Carter's interest in continuing and perhaps even strengthening the EIS program, and in view of forthcoming deliberations over such proposals on Capitol Hill, it is appropriate to review the record in order to learn what has been accomplished to date and what might be done to make such efforts more effective.*

James C. Miller III is a resident scholar in the Center for the Study of Government Regulation at the American Enterprise Institute. From October 1975 to January 1977, he was an assistant director of the Council on Wage and Price Stability. In that capacity he had a major responsibility for President Ford's Inflation Impact Statement Program.

* A thorough assessment of the program is contained in Thomas D. Hopkins, *An Evaluation of the Inflation Impact Statement Program* (Washington, D.C.: Council on Wage and Price Stability, December 7, 1976).

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Background

During 1974, rising anxiety about "double digit" inflation stimulated popular and official interest in the problem and led President Ford, in one of his first steps, to convene a series of summit conferences on inflation. These meetings produced a variety of recommendations in September and October of that year.

At the same time, the unprecedented growth in federal regulation was also causing concern. The early 1970s had seen the creation of seven new regulatory agencies, including the Environmental Protection Agency (EPA), the Consumer Product Safety Commission (CPSC), and OSHA. Between 1970 and 1974 the number of pages in the *Federal Register* had grown from 20,036 to 42,422 per year; the number of pages in the *Code of Federal Regulations* had grown from 54,105 to 69,270; and some twenty-nine major regulatory statutes had been enacted (see summary and table on page 43, this issue). Many business leaders, academics, and policy-makers were urging that regulatory activity be given closer scrutiny and that careful attention be paid to the costs and benefits of major regulations *before* rather than *after* they become effective.

These two concerns came together at two inflation summit conferences attended exclusively by economists. At the first session (Washington, September 5, 1974), there was considerable discussion about the extent to which "sacred-cow" regulations constrained economic growth, created unemployment, and caused prices to be higher than they would have been otherwise. At the second session (New York City, September 23), Thomas G. Moore, senior fellow at the Hoover Institution and an AEI adjunct scholar, circulated a petition calling for the elimination of a long list of federal regulatory and legislative restraints. Included on the list were laws restricting competition in transportation and limiting supplies of energy, as well as regulations setting the maximum interest rates payable by financial institutions and mandating safety devices on new automobiles. This petition was signed (with minor qualifications in some instances) by twenty-one of the twenty-three economists in attendance.

Thus, worry over inflation—and over regulation as a factor contributing to it—was the major reason the EIS program was established. But the officials responsible for the program were after more than a simple tracing through of the cost impact of proposed regulations and legislative recommendations.* They wanted to use the requirement to improve agency decision-making, and this meant getting the agencies to address the costs and benefits of their proposals. What program officials wished to avoid was the tendency for agencies to serve special constituent interests, often at great cost to the general public; to view the objects of their regulations as natural enemies, to be dealt with punitively; to forge ahead with regulatory and legislative proposals without knowing enough about the problem being addressed or the effects of the proposed solution; and to resist suggestions for alternative, more efficient ways of dealing with economic problems.

In briefings on the program, agencies were told that a proposal need not be considered inflationary simply because it might generate costs. Rather, if the proposal would increase real output (that is, generate tangible and intangible benefits in excess of costs), then in a real sense it was *anti-inflationary*, but if the action would decrease real output (that is, generate costs in excess of benefits), it was inflationary. Agencies were not required under the program to place exclusive, or even primary, reliance in their decision-making on cost-benefit calculations, for such a requirement could have been imposed only through legislation. Nevertheless it was believed that requiring agency officials to address costs and benefits systematically would make them more sensitive to these issues.

A first step in the program was to establish criteria for determining whether a proposed regulation or legislative recommendation should be considered "major." Obviously, to attempt assessments of *all* proposals would spread resources far too thin. So a principal

* These officials were under no illusion that the program would *solve* the inflation problem, or even make a substantial contribution for that matter. In contrast with fiscal and monetary policy, regulation has a very small effect on the rate of inflation. But for a given impact on that rate, regulation often has a greater effect upon consumer welfare because it operates directly upon the real supply of goods and services rather than working through aggregate demand.

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objective was to flag for analysis (and possible reconsideration) those proposals having costs greatly exceeding benefits. Since it tends to be easier to make a preliminary estimate of costs than benefits—especially at the initial stage of a proposal—the criteria focused on this aspect. Although supplemental criteria were developed, nearly every EIS issued during the first two years of the program was triggered by a preliminary finding that the proposal would cost $100 million during the first year it would be in effect or $150 million during the first two years.

Each EIS was required to analyze the proposal's estimated costs *and* benefits. These estimates were to include intangibles as well as tangibles and were to be expressed in dollar terms whenever possible. The EISs also had to review the costs and benefits of alternative approaches for achieving the same goal.

The administration of the EIS program was decentralized. Each agency was responsible for determining which of its proposals was major and for preparing the statements. Upon request, statements on proposed legislation were given to the Office of Management and Budget (OMB) and those on regulatory proposals were given to CWPS. Eventually, agencies were required to certify in the *Federal Register* that the inflationary impact of their proposed regulations had been considered and, in the case of major proposals, that an EIS had been prepared; also, upon request, agencies had to explain to CWPS why, in their judgment, a proposal was not major.

Finally, since the program was a presidential initiative established by executive order, it applied only to executive-branch agencies, and not to the independent regulatory agencies such as the Interstate Commerce Commission (ICC) and the Civil Aeronautics Board (CAB). The independents were urged to conform with the program, but each invoked its right not to be bound by it. Also, unlike its sister program, the Environmental Impact Statement, the EIS did not provide grounds for court action. As ultimately resolved in the *Independent Meat Packers* case (8th Circuit, 1975), an agency's failure to complete an EIS when required or to prepare one conforming to the specifications of the program could not be used to overturn a regulatory decision. In essence, conformance with the program depended on agency support and "policing" by CWPS and OMB.

Experience with the Program

As of mid-April 1977, a total of sixty-five EISs had been prepared—fifty-seven for proposed regulations and eight for proposed legislation. The table (see page 20) lists the date each of these analyses was completed, the responsible agency, the subject matter, and whether the proposal was regulatory or legislative. As can be seen, most EISs have been prepared by a handful of agencies—notably the U.S. Department of Agriculture (USDA), EPA, and OSHA. This reflects the important role these agencies have played recently in generating regulations and legislative proposals.

The quality of the individual EISs varies considerably. Some are quite detailed, broad in scope, and analytically sophisticated. But altogether too many are unduly brief, fail to address the relevant issues, and contain grossly defective analysis. Part of the explanation is that some agencies—for example, EPA and the Department of Transportation—have devoted substantial analytical resources to the task, while others—for example, USDA and the Food and Drug Administration (FDA)—have not. This, in turn, reflects the agencies' relative commitment to the program. While some have given it strong support, others have been hostile to it or, at best, have viewed it as a necessary hurdle.

Overall, the analyses contain reasonably good estimates of costs, but their assessments of benefits are weak, and alternatives are usually ignored. Typically, of course, costs are easier to analyze than benefits and alternatives. But the reluctance of some agencies to go beyond analyzing costs appears to be caused more by pressures from constituents than by an inability to cope with the technical problems of economic analysis. This seems particularly true of OSHA, which, despite repeated criticism from CWPS and OMB, steadfastly refuses to attempt monetary estimates of benefits or to analyze alternatives. Apparently, organized labor believes that its interests are better served by detailed, stringent standards, even though such standards may prove very costly, and objects to having OSHA, or anyone else, perform careful benefit estimates or analyze alter-

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natives, either of which might make the proposed standards seem less desirable. For instance, taking a strong position on approaches for reducing worker exposure to harmful substances, organized labor supports the installation of "engineering controls" (exhaust fans, enclosed transport, et cetera) rather than the use of "personal protective devices" (respirators, gloves, special suits, et cetera). Research by CWPS economists indicates that almost invariably the latter approach can reduce worker exposure at a small fraction of the cost of engineering controls.

Has the EIS program improved agency decision-making? It may be too early to tell. Since the gestation period for a proposed regulation or law is generally several years and since the program has been in full swing for only two years, we do not have enough cases to make a definitive judgment. Furthermore, in evaluating the program we are dealing with a very subjective output—the quality of decision-making. Also, even if adequate "before" and "after" comparisons were possible, we must be careful about attributing changes solely to the program; obviously, many factors could have intervened, such as worse or better regulatory appointments, political pressures from the administration and the Congress, and changes in the relative effectiveness of adversaries in regulatory proceedings. These problems make rigorous evaluation impossible at this stage, leaving us with personal and unsystematic appraisals from those who have observed the program or participated in it.

On August 3, 1976, CWPS asked for public comments on the EIS program by means of a notice in the *Federal Register*. Thirty-one replies were received, all favorable. These included comments from Senator Hubert H. Humphrey (then chairman of the Joint Economic Committee of the Congress) and a number of manufacturers and trade organizations. No replies were received from labor organizations, but it was widely reported in the press that certain labor leaders, including George Meany and Leonard Woodcock, were openly hostile to the program, especially as it affected OSHA.

About the same time, CWPS solicited the views of key personnel at the agencies, and followed up with a score of in-depth interviews with agency staff members responsible for the program. In addition, several agencies commented on various drafts of the report prepared by an evaluation team headed by Thomas Hopkins of CWPS. From these various comments we learned several things about how the program is functioning.

First, officials at all of the agencies, except for two, wished the EIS program to continue. Generally, they found the analyses helpful to them in weighing the component parts of a proposal and in making trade-offs to reduce the cost of meeting a given objective. They also found the analyses useful in defending a decision not to adopt as strong a regulation or legislative proposal as some of their more extreme constituents would have liked. This appears to be the primary reason why OSHA supported the program, albeit reluctantly.

The two agencies that formally opposed the program were USDA and the Federal Energy Administration (FEA). Indeed, in late August 1976 the USDA unilaterally stopped complying with the program, arguing that it represented "meaningless paperwork" and denying that regulation could have any impact on inflation. Such an attitude is, perhaps, understandable since, by their very nature, many USDA regulations that come under the EIS program—agricultural marketing orders, price support programs, and the like—can be shown to generate costs in excess of benefits. The reason for the FEA's strong opposition to the EIS program was different. At that agency the program was viewed as an impediment to the deregulation of petroleum prices, despite efforts by those responsible for the program to assure FEA officials that in a relevant sense such action would be *anti*-inflationary—that is, it would stimulate production and reduce excess demand. A major problem was FEA's dependence on macroeconomic, econometric models for predicting the outcomes of policy changes. Such models, by their very design, indicate a price-enhancing effect for deregulation. Moreover, officials were concerned about the public's perception of the effects of deregulation, and in their view the EIS simply drew attention to rising petroleum prices.

A second thing we learned from comments by agency officials and the public is that the program is not well integrated into the proc-

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ess of formulating proposals and making decisions about them. Typically, an EIS is prepared *after* a proposal has been drawn up and thus the analysts' task becomes one of justifying the approach taken. One reason for this is that usually the initiative for a new regulation or legislative proposal is taken not by the agency's economists or policy analysts, but by its lawyers and administrators. Their focus tends to be upon meeting the procedural requirements of timeliness, due process, the weighing of constituent interests, and defensibility in the courts, rather than upon the economic costs and benefits of their actions. Thus, the decision-making process often proceeds along two, almost distinct tracks—one for the decision-makers and one for the analysts. It is especially lamentable that typically the EIS is not relied upon as an input at the proposal formulation stage, since that is the time when information on costs, benefits, and alternatives is most likely to affect the ultimate decision. Once an agency has gone into print with its original proposal, the chances it will take a new direction are very slim.

Not surprisingly, then, a third major thing we learned is that the program receives higher marks from agency economists and policy analysts than from lawyers and administrators more directly responsible for the decisions. The lawyers' interest is to ensure ample discretion for the ultimate decision-maker and to minimize the risk that decisions will be challenged and perhaps overturned in court. They see the EIS as narrowing that discretion and as providing a potentially damaging piece of evidence in court. (For this reason, there is some reluctance to make EISs public.) On the other hand, economists and policy analysts generally see the EIS as strengthening their hand within the agency. It may give them somewhat more influence on policy decisions, and it often leads to an increase in their share of agency resources. The program also tends to be supported more strongly by senior officials in the agencies than by junior officials—partly because it is regarded as a means of "controlling the bureaucracy" and partly because it is a presidential program. Senior officials, as political appointees, are more apt to reflect presidential concerns about policy and the responsiveness of the bureaucracy than are employees protected by the Civil Service system.

The fourth thing we learned is that the program costs the agencies little in terms of resources. One reason is that the OMB circular promulgating the program stated that it would be met within the existing budget. The argument was that agencies already possessed a capability for economic analysis and that the EIS program would merely redirect that effort. Predictably, this has proved to be a bone of contention, and nearly every agency has urged that this policy be reconsidered. It appears, however, that few additional resources have been required. Existing policy staffs have been utilized a bit more intensively than they were, with their efforts supplemented on occasion by other personnel in the agency. The major exception is OSHA, which has contracted out its EISs, often at six figures. But even at OSHA *some* economic analysis would have been done in the absence of the EIS program.

On the basis of these conclusions and my own experience with the program, a tentative assessment may be made. First, as noted, the costs of the program appear to be low. Second, despite wide variations among agencies, there is some evidence, albeit highly subjective, that the program is having a substantial effect. Policy-makers now appear to be taking the economic implications of their proposals more seriously than they used to. In agency discussions and in formal proceedings, the EIS is serving as a rallying point for those arguing that regulation should be consistent with economic efficiency. The EIS is often an important component of CWPS filings before regulatory agencies—and, because CWPS is part of the Executive Office of the President and because its interventions are highly publicized, it has considerable clout. Moreover, although agencies seldom alter their proposals once announced, there have been cases where, arguably, the EIS and the attention drawn to it have caused the ultimate outcome to be different than it otherwise would have been. More important, an agency's concern that its EIS may be criticized and that the analysis may undercut, rather than support, its proposal has led to closer coordination between the lawyers and economists at the proposal formulation stage—and, therefore, to more carefully considered proposals and better analyses. Thus, summing up, it appears that the benefits of the program substantially outweigh the costs.

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Where Do We Go from Here?

When contemplating the future of the EIS program, one should keep in mind that economic analysis is merely one instrument for improving the quality of decision-making and that there are others—including better regulatory appointments, greater oversight by OMB and the Congress, and revisions in the Civil Service system to improve the quality and accountability of agency staff. While the EIS program alone cannot produce perfection, it can be—and, as we have seen, has been—a useful device. It should be continued. It should also be improved.

First, steps should be taken to improve the overall quality of EISs. Specifically, minimal standards should be established. Clearly, decision-making is not aided if the analysis on which it is based is incompetent. This objective could be addressed by requiring that regulatory agencies, before taking action, obtain CWPS or OMB approval for the quality of their analysis (not the desirability of the proposal). Any impasse between CWPS or OMB and the initiating agency could be resolved by the Economic Policy Group (EPG) or some other representative designated by the President. Changes of this kind might require legislation.

Second, steps should be taken to ensure that the EIS is utilized as an input into the regulatory decision-making process—especially at the proposal formulation stage. One way of bringing this about would be to require agencies to submit their EIS evaluations to CWPS (or perhaps some other group like the EPG) *prior* to publication in the *Federal Register*. This would give proposal formulators the opportunity to draw upon outside expertise and would provide an extra incentive for them to utilize the analyses.

Third, the EISs should be made public and should be featured more prominently by the agencies. As mentioned earlier, the possibility that an EIS will be criticized spurs agencies to improve their analyses and make better use of them. Formal EISs should accompany major legislative proposals sent to the Congress by the administration. In the case of regulatory proposals, the formal EIS (or, if lengthy, an executive summary) should be published in the *Federal Register*.

Fourth, the program needs to be extended to *existing* regulations and programs. This could be done without legislation, utilizing OMB in its normal management and budget roles. Or, to maintain flexibility and avoid undue bureaucratization, CWPS and/or OMB might be given explicit authority to request from each agency each year a limited number of analyses of existing regulations or programs.

Fifth, the program should also be expanded to include the independent regulatory agencies —for example, the ICC, the CAB, the Federal Power Commission, the Federal Communications Commission, and the Federal Trade Commission. These agencies generate important legislative and regulatory proposals whose overall quality could be enhanced by a rigorous application of economic reasoning. This recommendation also would require legislation.

Sixth, all agencies should have the discretion to consider costs and benefits in developing their regulatory proposals and in making their decisions. This would mean, for example, (1) repealing the "Delaney amendment" to the Food, Drug, and Cosmetics Act (which requires the FDA to ban any food additive found to be carcinogenic, regardless of the benefits and costs of such a ban) and (2) modifying the Clean Air Act (which, as it is interpreted by EPA, requires the agency *not* to consider costs and benefits in certain instances).

Seventh, Congress should require that, according to reasonably informed judgment, major new regulations have favorable cost-benefit ratios and meet their given objectives at the lowest cost, considering all the available alternatives. Along with this, Congress might grant interested parties the right not only to appeal in the federal courts but to have the regulatory decision determined in the courts (that is, *de novo* review) if there were clear and convincing evidence that the agency had failed to consider the benefits and costs of the proposal.

IN PRACTICE, regulatory decision-making and legislative proposal-making fall far short of the theoretical ideal. Our objective should be to make them as rational as possible, and the EIS technique is an important contribution to that end. To attain its full usefulness, however, it should be strengthened by administrative action and supplemented by legislation.

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ECONOMIC IMPACT STATEMENTS COMPLETED BY FEDERAL AGENCIES

Date EIS Completed	Agency	Subject	Nature of Proposal
March 1975	DOC	proposed Patent Modernization and Reform Act	legislation
March 1975	USDA	standards for beef grading	regulation
April 1975	FEA	proposed Energy Conservation and Production Act	legislation
May 1975	USDA	support for U.S. agricultural exports	regulation
May 1975	USDA	tobacco price supports	regulation
June 1975	USDA	peanut price supports	regulation
June 1975	HUD	construction standards for mobile-home safety	regulation
July 1975	FEA	proposed Electric Power Facility Construction Act of 1975	legislation
July 1975	USDA	U.S. agricultural export program of Commodity Credit Corporation	regulation
July 1975	DOL	proposed Unemployment Compensation Amendments Act	legislation
July 1975	EPA	registration of pesticides	regulation
August 1975	DOL	proposed Work Incentive Program Amendments Act	legislation
September 1975	EPA	drinking water standards	regulation
October 1975	EPA	motorcycle emissions	regulation
October 1975	EPA	effluents from offshore gas and oil production	regulation
October 1975	USDA	milk price supports	regulation
October 1975	USDA	labeling of meat and poultry products	regulation
October 1975	USDA	support and regulation of cotton crop program	regulation
October 1975	DOT	proposed Aviation Act of 1975 (regulatory reform)	legislation
November 1975	EPA	maintenance of ambient air quality standards	regulation
November 1975	EPA	coal mining effluents	regulation
November 1975	HUD	mortgage insurance and assistance	regulation
November 1975	DOT	proposed Northeast Regional Railroads Additional Service Act	legislation
January 1976	USDA	support for U.S. agricultural exports	regulation
January 1976	EPA	effluent guidelines for paper industry	regulation
January 1976	HEW/FDA	ban of diethylstilbestrol (DES) in cattle feed	regulation
February 1976	HEW	discrimination against handicapped persons	regulation
February 1976	DOL/OSHA	worker exposure to coke-oven emissions	regulation
February 1976	FEA	exemption of residual fuel oil from mandatory petroleum allocation and price regulations	regulation
February 1976	EPA	standards for measuring evaporative hydrocarbon emissions from automobiles	regulation
February 1976	EPA	limitations on organic-chemical effluents	regulation
March 1976	USDA	milk price supports	regulation
March 1976	USDA	modifications in food stamp program	regulation

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ECONOMIC IMPACT STATEMENTS COMPLETED BY FEDERAL AGENCIES (continued)

Date EIS Completed	Agency	Subject	Nature of Proposal
March 1976	DOD/CE	permits for dredge-and-fill operations	regulation
March 1976	EPA	emissions from light-duty trucks	regulation
April 1976	HEW	Medicaid reimbursements to nursing homes	regulation
April 1976	HEW/FDA	banning of nitrofurans in chicken feed	regulation
April 1976	DOL/OSHA	worker exposure to industrial noise	regulation
April 1976	DOL/OSHA	worker exposure to inorganic arsenic	regulation
May 1976	FEA	proposed Energy Independence Authority Act	legislation
May 1976	USDA	tobacco price supports	regulation
May 1976	DOT	financing of rehabilitation of railroad facilities	regulation
June 1976	EPA	guidelines for iron and steel effluents	regulation
June 1976	EPA	effluents from photographic processing	regulation
June 1976	FEA	guidelines for federal support of state energy conservation plans	regulation
July 1976	DOT/NHTSA	occupant crash protection (air bags)	regulation
July 1976	FEA	definition and allocation of nonproduct cost increases	regulation
August 1976	USDA	support for U.S. agricultural exports	regulation
September 1976	EPA	effluents from pesticides	regulation
September 1976	FEA	contingency plan for gasoline and diesel-fuel rationing	regulation
November 1976	EPA	limits on polychlorinated biphenyl (PCB) effluents	regulation
November 1976	FEA	exemption of motor gasoline from mandatory allocation and price controls	regulation
December 1976	EPA	guidelines for effluents from onshore oil production	regulation
December 1976	EPA	noise emissions for wheel and crawler tractors	regulation
January 1977	EPA	dust emissions from grain elevators	regulation
January 1977	DOC	guidelines for federal support of coastal energy impact programs	regulation
January 1977	DOL/OSHA	occupational exposure to sulfur dioxide	regulation
January 1977	DOT/FAA	abatement of airport noise	regulation
February 1977	FEA	allocation of increased costs to gasoline	regulation
February 1977	FEA	entitlements program for strategic petroleum reserve	regulation
February 1977	DOL/OSHA	occupational exposure to lead	regulation
March 1977	FEA	incentives for industry to switch from oil and gas to coal	regulation
April 1977	USDA	milk marketing order in the New York-New Jersey area	regulation
April 1977	HEW/FDA	banning of saccharin and its salts	regulation
April 1977	FEA	consistent control treatment for Californian and Alaskan crude oil	regulation

Source: Council on Wage and Price Stability and Office of Management and Budget.

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Protection or Overprotection in Drug Regulation?

The Politics of Policy Analysis

David Seidman

"If thalidomide cured leukemia, it would be on the market today," or so a Food and Drug Administration lawyer told me.[1] The claim is surely correct. But thalidomide is only a sedative, and an army of deformed babies is too high a price to pay for the bit of calm that thalidomide might produce.

The decision to approve or prohibit the marketing of a drug is often a difficult one, because no drug is perfectly safe if it is powerful enough to be useful. Aspirin, for example, "has been said or shown to interfere with platelet function, to cause allergic reactions in the sensitive, to induce exfoliation of renal epithelial cells, to initiate gastric and to exacerbate duodenal ulcer, and to aggravate liver disease under certain circumstances," and is known to cause gastric bleeding in normal use.[2] The decision to approve a drug turns on its possible risks and benefits to health and even life. Assessing the balance is difficult, because neither the risks nor the benefits can be known precisely, and in any case depend upon values which cannot easily be stated or quantified and which may not be consensual.

Since 1962, U.S. policy on this matter, roughly speaking, has been to allow marketing of only those pharmaceuticals demonstrated to be safe *and effective*. The way this policy is to be carried out by the Food and Drug Administration (FDA) is, of course, not fully specified by law: the FDA writes regulations to implement the law and has discretion within those regulations. Both the legislated policy and the way the FDA implements it have effects going well beyond the availability of any particular drug, because FDA decisions on marketing become part of the costs of developing new drugs.

Criticism of both the legislated policy and FDA's actions is common. There are, in broad outline, two schools of critical thought on drug regulation. One holds that drugs are too readily approved for marketing, the other that they are too readily rejected. There is, unfortunately, no obvious way to decide who is right, but several attempts have been made. This essay examines these attempts and their exceedingly chilly reception by the policy community. This is, then, a case study in the politics of policy evaluation.

The Regulatory Context

An understanding of the issues involved requires some familiarity with the nature of an unregulated market for pharmaceuticals and the nature of the regulatory structure.

An Unregulated Market for Pharmaceuticals. The ultimate consumer of pharmaceuticals, the patient, is not like the consumer in the classical model of the free market because, presumably incompetent himself to evaluate pharmaceuticals, he must leave the choice to

David Seidman is a staff associate at the Social Science Research Council's Center for Coordination of Research on Social Indicators in Washington, D.C. A political scientist, he taught at Princeton University and has published articles on social indicators, crime statistics, administrative structure, and statistical methodology.

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the doctor. The patient-consumer is therefore not sovereign. Rather, it is the doctor's preferences, willingness to run risks, and information that govern drug selection.

As for the doctor, he makes the choices but does not bear the financial and other costs of taking the drugs. Being partially insulated from the consequences of his actions, he may not have the consumer's normal incentive to be well informed. Without conducting large controlled experiments, he will generally not learn greatly from experience, and the professional literature is too vast for anyone to master. Typically, the doctor relies heavily upon information provided by the drug manufacturer.

A pharmaceutical firm will provide doctors with vast quantities of information because sales depend upon it. But the firm has less incentive to provide information that is full and accurate because doctors and patients cannot independently check its reliability or adequacy, at least not in the short run. Word may eventually get around, but until it does, manufacturers operating in an unregulated market are generally free from the consequences of providing misleading information. Tort law, a potential spur to accurate information, is difficult to use against manufacturers of prescription drugs. Concern for reputation, another spur, also seems to be insufficient. Thus, manufacturers generally make more extensive promotional claims but provide less information about potential hazards when selling their drugs in the relatively free markets of Latin America than when selling in the United States where promotional information must meet FDA standards.[3]

A free market for prescription drugs is thus imperfect, and may even be perverse. Regulation seems required to correct the imperfections, particularly those related to information.

Regulation before 1962. The first food and drug act, that of 1906, regulated a drug market that was chaotic and dangerous. Three decades later, the Food, Drug, and Cosmetic Act of 1938 created something resembling the present regulatory structure. Under it, manufacturers had to file a New Drug Application (NDA) with the FDA presenting evidence that the drug was safe for use under certain specified conditions. Unless the FDA rejected the application within sixty days (and the grounds for rejection were limited), the NDA became "effective," and the drug could be marketed. (Actually, although the distinction is not often important, it was the entry of a "new drug" into interstate commerce which the NDA governed.)

In order that the drug could be tested before marketing, investigations by "qualified" investigators were exempt from these requirements. The tests—including those on human subjects—were, for all practical purposes, unsupervised by the FDA or anyone else.

The act spoke only of safety, but safety is closely linked to the effectiveness of a drug, so the FDA in principle took effectiveness into account in considering the NDA. FDA Commissioner Larrick explained the pre-1962 FDA approach in testimony given in 1964:

> If we had used the term "safety" in the dictionary definition, we would have taken nitroglycerin off the market, sulfanilamide off the market, and drugs of the value of insulin off the market. It was obvious to us as administrators that was not what Congress intended. So taking what we thought was the legislative history of this section into account, we then announced to the world . . . that in dealing with lifesaving drugs we would have to consider whether a drug was effective in considering safety.[4]

Attention to effectiveness was, however, limited: the FDA could not require evidence of effectiveness in an NDA.

The system allowed widespread use of a drug—for investigational purposes—with virtually no government controls, required some evidence that the drug was safe before it could be marketed, and almost totally ignored the drug after marketing approval was given. The consumer-patient therefore had some reasonable assurance that, at one point in their history, the drugs he bought had been shown, on the basis of some evidence, not to be strikingly unsafe. There was less (if any) assurance that the drugs were useful. And there was no assurance of safety or efficacy in the case of drugs which the consumer did not buy, but rather was given by a doctor conducting an informal bit of research with an "investigational" drug.

Thalidomide. This was the regulatory structure that existed when thalidomide was kept off the

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market in the United States, thereby preventing here the sort of tragedy which occurred elsewhere. But the American experience with thalidomide was unsettling anyway. Disaster was prevented through what would appear to have been a combination of luck and the sort of dedication and courage which any system would be unwise to assume as typical. (FDA medical officer Dr. Frances O. Kelsey blocked the marketing of thalidomide on the grounds that it had been inadequately tested, for which she received a distinguished government service medal from President Kennedy.) Furthermore thalidomide had been widely distributed and used within the United States under the investigational exemption. Over 2.5 million "experimental" thalidomide tablets had been distributed to 1,200 physicians, about 20,000 patients had received thalidomide, and 624 were reported as pregnant. In all, there were ten deformed babies born to American women who had received thalidomide from domestic sources and taken it during the critical first three months of pregnancy.[5] Physicians were under no legal obligation to inform those patients who took the drug that it was experimental.

The thalidomide incident (along with other events) suggested at least four conclusions. First, the regulatory structure prior to 1962 allowed somewhat precipitous investigational use of drugs in humans: often it occurred before the potential benefits of tests on animals were exhausted. Second, investigational use was, at least in some cases, extremely casual. Third, the evidence upon which the FDA relied in considering NDAs was often weak, much of it amounting to testimonials (or "uncontrolled clinical trials") rather than careful studies. Fourth, the procedure for considering NDAs was not well-designed either to facilitate detailed consideration of the evidence by FDA medical officers or to allow the FDA to resist industry pressures for approval of drugs. The Kefauver-Harris drug amendments of 1962 were designed to take account of these points and others.

Regulation after 1962. Under the 1962 amendments, premarketing requirements and implementing regulations became considerably more elaborate than they had been before. The sequence is now roughly as follows.

A new substance is invented (or a new use found for an old one). Various studies of safety and efficacy are carried out in the laboratory, without the use of human subjects. Then, in order to receive permission for human testing (actually permission to introduce the drug into interstate commerce for the purpose of human tests), the manufacturer must file with the FDA a Notice of Claimed Exemption for a New Drug (IND). This document, which describes the testing already done and sets out a detailed plan for subsequent testing, is a crucial addition to the regulatory structure. The proposed tests must be "adequate" and are subject to elaborate rules, including one requiring consent of the subjects. Once the IND receives FDA approval and becomes effective, the tests which will later provide the basis for the NDA may begin.

Following testing in the IND phase, the manufacturer submits the NDA. Another crucial difference between the old and the new system is found here: the tests must not merely demonstrate that the drug is safe, but also provide "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested . . .," where " 'substantial evidence' means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved. . . ." [6] This can be interpreted as a requirement that experimentation be conducted according to the highest standards of design and analysis. (Achieving this standard is difficult. Indeed, a statistical consultant to the FDA told me that if the highest standards were applied, none of the tests that he examines would be passed. It is notoriously difficult to carry out a perfect experiment outside the laboratory.)

In principle, only when safety and efficacy have been established according to these rigorous standards is the NDA approved and the drug released for marketing.[7] Even if the standards are applied with something less than full rigor, the cost (in both time and money) of developing a new drug and bringing it to market can be very high:

The impact of these requirements on a

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drug maker was considerable. For example, a Parke-Davis official reported that when the company first marketed a particular epinephrine preparation in 1938, all it had to submit was a 27-page report concerned primarily with safety. In 1948, when it introduced a new expectorant, only a 73-page report was required. Another new drug marketed in 1958 needed a 430-page submission. But in 1962, when Parke-Davis requested FDA approval of its contraceptive Norlestrin, it had to present a report amounting to 12,370 pages. And in 1968, when approval was requested for its new anesthetic Ketamine, the required documents totaled slightly more than 72,000 pages in 167 volumes.[8]

It is, in large measure, these costs which raise the question of protection and overprotection.

Protection or Overprotection: The Dilemma of Regulation

The present regulatory structure for new drugs is designed to prevent physical harm by keeping "unsafe" drugs off the market. It is also designed to prevent the physical harm which may result from taking an ineffective drug—a harm which may occur simply because an effective drug, if available, would have cured the disease—and the economic harm of spending money on drugs which do no good. But these worthy aims cannot be achieved without some costs. The cost of bringing a drug to market has been substantially increased by the new testing requirements. Either manufacturers absorb this new cost, which means lower profits, or part or all of the cost is recovered through the market, which means higher prices. In some cases, for example, that of the drug treating a rare disease, these costs may be unrecoverable. If the cost of developing new drugs has increased, standard economic theory would suggest that there is, in consequence, less development.

There are also costs in time. The requirement of more extensive testing, along with the resulting need for more consideration by the FDA, must delay the movement of new drugs to the market. This is not surprising: many who supported the 1962 amendments argued that drugs were being brought onto the market entirely too quickly. However, suppose a safe and effective new drug is developed. The period during which it is being tested is a period in which its therapeutic benefits are not generally available. As an American Medical Association spokesman put it, "it is entirely possible that more lives could be lost by keeping a valuable drug off the market during extensive clinical trials than would be saved by gaining a precise knowledge of the exact type and incidence of all side effects." [9]

One final potential cost should be mentioned. Under the present regulatory structure, it is almost always the case that a drug is either not permitted on the market or is permitted on the market with almost no controls over its use by doctors. We enforce, so to speak, a simple all or none choice.[10] But the pattern of a drug's effects is not that simple. A drug may help some individuals while injuring others. The doctor, exercising care and judgment (as he sometimes does not), may be able to determine that a dangerous drug is in fact not so dangerous to his particular patient. Thus an absolute ban against a generally unsafe drug may deprive individual patients of important therapeutic benefits. As Wardell and Lasagna put it, "this type of risk-benefit decision should ultimately be made by single physicians for individual patients, rather than by a regulatory agency for society as a whole." [11] Even if this recommendation is not accepted, it is clear that making decisions for society as a whole does not necessarily maximize the expected benefit for particular individuals.

The present structure for regulating the safety and efficacy of new drugs entails . . . certain costs in precisely those areas where we seek benefits through regulation—that is, in terms of the well-being of the patient. The more exacting the requirements of regulation, the higher these costs are likely to be.

The present structure for regulating the safety and efficacy of new drugs entails, then, certain costs in precisely those areas where we seek benefits through regulation—that is, in terms of the well-being of the patient. The more

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exacting the requirements of regulation, the higher these costs are likely to be. An absolute standard of safety would prevent all drugs from being marketed. On the other hand, a permissive standard that amounted to allowing anything and everything on the market might recreate the conditions that led to regulation in the first place. The ideal is presumably somewhere between the extremes of no drugs and no regulation, at a point where the benefits of regulation in terms of consumer protection still outweigh the costs.

But where is that point? This question has stirred increasingly lively debate ever since the implementation of the 1962 amendments—a fact which is not surprising. Therapeutic accidents are dramatic. The amendments have profoundly altered the operating conditions of a major industry, and they impinge upon the status of doctors as well. Moreover, they are vigorously supported by consumer groups. Finally, the recent revival—on the campus and in policy circles—of interest in the nature and consequences of government regulation in general has also fed the debate.

Let us look at four different approaches taken in the debate on evaluation of drug regulation and then consider how officials within the policy community reacted to the approaches taken outside that community.

Four Alternative Approaches

The Economist. As I described the problem above, evaluation of the 1962 amendments is a relatively straightforward question of costs and benefits. Chicago school economist Sam Peltzman has produced such an evaluation.[12] It is a highly technical work of empirical analysis, relying upon both the economic theory of consumer surplus and data analysis linked to a long chain of assumptions. I attempt here only a very crude sketch.

Consider efficacy first. Peltzman notes that the amendments appear to assume that, before 1962, consumers (doctors) were making excessive purchases of new drugs—that is, their demand curves were "too high"—because they were acting upon exaggerated claims of efficacy. If the assumption were valid, demand would have fallen over time as consumers learned that the claims were exaggerated. Using data on market shares and prices for new and old drugs within therapeutic categories, Peltzman estimates pre-1962 demand curves for new drugs shortly after introduction and four years later. He finds little difference, and therefore concludes that there was in fact little waste as a result of ineffective drugs. Thus the potential gain to consumers that the amendments could have produced was small. The same analysis for the post-1962 period produces similar results—which implies the same conclusion.

This conclusion of small benefits implies that the initial demand for new drugs in the pre-1962 period was close to the "true demand." Peltzman then compares pre- and post-1962 initial demand for new drugs and finds that the new demand curve is lower. He attributes the decline to the reduction in information provided to the consumer, a reduction that has occurred because the 1962 amendments severely restrict the claims which manufacturers may make. Consumers, it is implied, would demand more of these new drugs if the 1962 amendments allowed more information. Since additional benefits to consumers would be generated through the additional demand, the effect of the amendments is a loss in consumer welfare. (Peltzman's analysis uses the more technical term "consumer surplus.")

Consumers also lose, Peltzman argues, for two additional reasons. First, the amendments retard innovation in drugs so that some drugs which would appear on the market were it not for the amendments do not appear. Consumers would benefit from these as well. To establish that a decline in innovation has in fact occurred, Peltzman analyzes the annual number of new chemical entities (a smaller category than new drugs) introduced, and con-

In sum, Peltzman finds [that the 1962 amendments have produced] both benefits and costs to the consumer. The benefit from decreased spending on ineffective drugs is estimated to be roughly $100 million annually, while the costs from a reduced flow of both drugs and information are roughly $300-$400 million . . . and those from decreased competition are roughly $50 million. . . .

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cludes that there has in fact been a substantial decline attributable to the amendments. Second, the amendments lead to higher prices for existing drugs, because the higher costs to new firms (or new drugs) of entering the market reduce competition.

In sum, Peltzman finds both benefits and costs to the consumer. The benefit from decreased spending on ineffective drugs is estimated to be roughly $100 million annually, while the costs from a reduced flow of both drugs and information are roughly $300–$400 million annually and those from decreased competition are roughly $50 million annually. Overall, there is a substantial net loss to the consumer.

The question of safety is more difficult to address, but Peltzman bravely makes the attempt. His strategy is to compare the cost of an occasional thalidomide tragedy with the costs of delay in the introduction of major therapeutic advances. The analysis is necessarily highly speculative, because no one knows how many major therapeutic disasters there would be with or without the amendments, what major therapeutic advances are or would be likely, how much they would be delayed, or how to put dollar values on death and disease. Peltzman thinks the safest conclusion is that the amendments have neither produced significant safety benefits so far, nor foreclosed or delayed extraordinary therapeutic advance. On the other hand, he suggests that the procedures required by the amendments go too far in avoiding risk, that we would probably be better off if we accepted a higher likelihood of thalidomide tragedies in return for speedier introduction of major therapeutic advances. Once again, the 1962 amendments are seen as providing a net loss to society.

In the discussion that follows, two points should be kept in mind. First, Peltzman focuses entirely upon results and ignores the process through which the FDA reaches its decisions. Second, he uses aggregate data almost entirely. He does not, except in the tentative discussions of safety, point to any single drug as exemplifying his points. He has chosen to avoid pharmacological issues, no doubt wisely—for he is an economist, not a pharmacologist.

The Pharmacologist. A second major line of criticism of the 1962 amendments concentrates on particular drugs. This approach is most closely associated with the name of William M. Wardell, professor of pharmacology, toxicology, and medicine at the University of Rochester.[13] Wardell's strategy is to compare the availability of drugs in the United States and in Great Britain in the post-1962 period. His assumption is that the patterns of regulation in the two countries were far more similar before the 1962 amendments than after.

Taking the 1962–71 decade, Wardell tabulates drugs introduced according to whether they were exclusively available in the United States, exclusively available in Great Britain, or available in both. He concludes that at least in numerical terms, the United States lagged considerably behind Britain. This, of course, may be good or bad for the United States, depending upon the value of the drugs foregone.

[Wardell concludes:] "In view of the clear benefits demonstrable from some of the drugs introduced into Britain, it appears that the United States has, on balance, lost more than it has gained from adopting a more conservative approach than did Britain in the post-thalidomide era."

Wardell approaches this problem of value in three ways. First, he examines the medical evidence on the uses, effectiveness, and safety of most of these drugs, generally concluding that they should have been available in the United States. Second, he surveys British and U.S. doctors and discovers that British doctors consider these drugs important, while U.S. doctors are generally unaware of them. In those cases where the U.S. doctors are aware of the drugs or of unapproved uses of available drugs, they generally think that the drugs should be available or the uses approved. Finally, he attempts an analysis of the safety question that is similar to Peltzman's except that it takes into account the impact of particular drugs actually available in Britain. He concludes that "it is difficult to argue that the United States has escaped an inordinate amount of new-drug toxicity by its conservative approach," and "it is relatively easy to show that Britain has gained by having effec-

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tive drugs available sooner." Furthermore, the costs to Britain of higher levels of adverse drug reactions have been small. "In view of the clear benefits demonstrable from some of the drugs introduced into Britain, it appears that the United States has, on balance, lost more than it has gained from adopting a more conservative approach than did Britain in the post-thalidomide era." [14]

Whereas Peltzman concludes that the 1962 amendments ought to be repealed, Wardell's recommendation is rather more complex. He would keep a regulatory structure, but he would rely less than we do today upon the all-or-none marketing decision and more upon release subject to postmarketing surveillance and he would institute new controls (or at least influences) upon the actual use of the drugs by doctors.

While Wardell speaks to the mechanism of regulation, his analysis is primarily in terms of results, not of the process through which they are achieved. In this it is similar to Peltzman's. It parts company with Peltzman in that it does not avoid pharmacological issues and does not provide an overall measure of the impact of the 1962 amendments, as Peltzman's measure of consumer surplus does.

The Politician. Evaluation of results is one way to judge the impact of regulation. Another way, generally less explicit, is to evaluate the specific regulatory process.

A process approach commonly found on Capitol Hill makes use of the political science model of interest-group conflict or pressures. (Model as used here means a simplified representation, or image, of reality, one which focuses on central elements and strips away nonessential detail. This simplification facilitates coherent analysis.) In this model, FDA decisions are seen as heavily influenced by drug industry pressures, by constant contact between regulators and regulated in which the regulated seek to have their drugs approved. This perspective is nicely captured by the following exchange between Senator Edward Kennedy and Ralph Nader:

> Senator KENNEDY. . . . Commissioner Schmidt of the FDA has put the question . . . that the agency is caught between the devil and the deep blue sea. On the one hand [there are] the pressures of the various drug industries, and on the other hand the harassment by active consumer groups. . . . Is [this] a fair description of the dilemma?
>
> Mr. NADER. Not at all.
>
> Senator KENNEDY. Are the two forces equal?
>
> Mr. NADER. They are basically magnified 1,000 times greater on the part of industry.[15]

This model has led many to conclude that the 1962 amendments do not provide sufficient protection for the public. And, indeed, some analyses of results appear to support this view and validate the model. It is possible, for example, to take almost any FDA decision approving a drug for marketing and demonstrate both that the evidence upon which the decision was based does not meet the rigorous standards supposedly required and that injury or death will result in at least some instances from use of the released drug. If the benefits resulting from the decision are ignored, any FDA drug approval will therefore appear to be unwise. And it is easy to ignore the benefits, because they are rarely so colorful or identifiable as the injuries that may be directly traced to the drug.

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Public display of these disasters has become a major congressional activity. As FDA Commissioner Schmidt has said, "The occasions on which hearings have been held to criticize approval of a new drug have been so frequent in the past ten years that we have not even attempted to count them." [16] The hearings serve two purposes, one within the context of the model and one outside it: they provide a counterweight to industry pressures, and they serve the publicity needs of congressmen. For both purposes, press coverage is essential. As one congressional staffer deeply

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involved in drug hearings told me, there is "no sense in having hearings unless you are going to get coverage." Since the hearings usually deal with dramatic subjects, that coverage is generally forthcoming (perhaps particularly in Washington, where Morton Mintz, himself a leading exponent of the interest-group or pressure model of FDA decisions, covers them for the *Washington Post*).

There is a variant of the pressure model which leads in a very different direction. It sees the balance of pressure as resulting in overprotection. Central to this view are precisely these "counterbalancing" congressional hearings, which teach bureaucrats that procrastination in approving new drugs is the route to salvation. As FDA Commissioner Schmidt has said, reflecting a view shared by industry:

> In all our history, we are unable to find one instance where a Congressional hearing investigated the failure of FDA to approve a new drug. . . . [T]he message conveyed by this situation could not be clearer. . . . Until perspective is brought to the legislative oversight function, the pressure from Congress for FDA to disapprove new drugs will continue to be felt, and could be a major factor in health care in this country.[17]

The pressure model, then, leads in two directions and implies two different answers to the evaluation problem.

The FDA Official. Another process approach to assessing a regulatory system holds that what is important is the procedure through which decisions are made: procedure determines substance. The approaches discussed above seem most congenial to the economist, the doctor, and the politician. This one seems peculiarly lawyerly, though it is shared by non-lawyers at FDA. The director of FDA's Bureau of Drugs has argued that to "be credible, regulatory decisions must not only be scientifically sound and legally correct. They must be made for the right reasons and result from a valid, open decision-making process administered by persons of integrity." [18]

In essence, the FDA's decision is a judgment of costs (or risks) and benefits. The problem, according to one official, is that cost-benefit analysis, though proper in principle, cannot be carried out because neither costs nor benefits can be quantified. Consequently, the only thing to do is to rely on proper procedures and a well-designed process. In recent years, the FDA has attempted to structure the process so that "a lot of reasonable people have input"—which has meant, in practice, the multiplication of advisory committees through which the best available judgment can be brought to bear on regulatory decisions. The result may be good decisions within the statutory framework. But if that framework is faulty, as Peltzman and Wardell suggest, the FDA's reliance on advisory committees does not meet the problem and the major questions of regulatory policy remain unanswered. It should be kept in mind, however, that in our political system, the place where these questions should be decided is the Congress and not at the agency level.

The FDA's reliance upon outside advice can also be explained as a means of diffusing responsibility for decisions. One FDA official has said as much: "the responsibility that is imposed on us by law is too heavy for a government agency to bear alone. When we speak of outside advice . . . what we are actually seeking is a means of widening the base of decision-making, and thus, broadening responsibility." [19] Even so, the view from the evaluation standpoint is that procedure determines substance.

Reactions and Interactions

As we have seen, the critiques that Peltzman and Wardell leveled at the status quo in drug regulation clashed head on with the perspectives of major policy officials within Congress and the FDA. A review of the clash provides useful insights on the impact of policy evaluation.

Reactions to Peltzman: The Nelson Hearings. The first major public response to Peltzman and the drug-lag theorists (other than Wardell, whose work had not yet been published) came in the form of five days of hearings held in February and March 1973 before Senator Gaylord Nelson's Subcommittee on Monopoly of the Senate's Select Committee on Small Business. This subcommittee had long been interested in pharmaceutical regulation, and its

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staff explicitly saw the hearings as a chance to refute criticism of the 1962 amendments, particularly that of Milton Friedman (who had publicized Peltzman's findings in a *Newsweek* column). In the view of staff members, Chicago-school economics is a closed deductive system at odds with the scientific method, so that Peltzman's findings were both without value and "dangerous." Senator Nelson's opening statement makes clear the purpose of the hearings: "Since these are serious charges, the subcommittee would be happy to have Dr. Dripps [who had charged the FDA with creating a 'drug lag'], Mr. Peltzman, and Mr. Friedman come to document them or withdraw them." [20] Nelson clearly preferred the second alternative.

The major burden of discrediting the "charges" fell to the FDA itself, which provided the first witnesses. The FDA's defense of American drug regulation had five major points.

(1) Innovation has not declined as a result of post-1962 practices. The FDA noted that the decline began before 1962. (Peltzman had realized this. He modeled innovation as a response to growth in the demand for drugs and showed that the relationship changed with the amendments. The FDA did not comment on this.) Then the FDA argued that Peltzman (and others) were looking at the wrong data: "The relevant question is not now and never has been how many new drugs are marketed each year, but rather how many significant, useful and unique therapeutic entities are developed. . . . [T]he rate of development and marketing of truly important, significant, and unique therapeutic entities in this country has remained relatively stable for the past 22 years. . . ." [21] (Responding to this some time later, Peltzman pointed to the highly subjective character of the criteria and noted that "an unpublished version of the same FDA listing" shows a statistically significant shift.) [22]

(2) In any case, if there is a drug lag, it comes about because the 1962 amendments require decent testing of drugs rather than "subjective impression"; the alternatives to controlled clinical trials are not as scientifically reliable. The fault, if there is one, does not lie with the FDA. (While Peltzman had never suggested it did, some of the drug-lag theorists had.)

(3) In any case, comparison with other countries does not show that the United States has been hurt by the amendments. An exchange between Senator Nelson and Dr. Henry Simmons, then director of FDA's Bureau of Drugs, illustrates the argument:

> Senator NELSON. Are you aware of any significant drug entity marketed in any foreign country that is not available here and for which there is no viable alternative available here?
>
> Dr. SIMMONS. . . . I do not know of such a drug and the key phrase there, Mr. Chairman, . . . is known to be safe and effective.[23]
>
> . . . In our judgment, there is no condition amenable to drug therapy that cannot be treated as safely and effectively in this country as any place in the world. The American public is not deprived of significant therapeutic drugs whose safety and effectiveness have been adequately substantiated.[24]

The key phrase is indeed "known to be safe and effective," for it comes close to reducing the FDA's position to a tautology. In order for the FDA to consider a drug as "known to be safe and effective," it must consider the evidence of safety and effectiveness to be sufficient to justify approval of the drug for the U.S. market. (In theory the FDA could be aware of such evidence even though no NDA had been submitted, but this is a rare situation.) The more important question is whether drugs are available in other countries which ought to be on the U.S. market even though they are not, by the FDA's standards, "known to be safe and effective."

"Viable alternative" is also a key phrase. At the time of the hearings two of the drugs marketed in Great Britain but not in the United States were practolol and oxprenolol, both "beta-blockers," a type of cardiovascular drug. An alternative to these drugs is propranolol, another beta-blocker which was available in the United States. Is propranolol a "viable alternative," as Senator Nelson and the FDA suggested? Perhaps, but "both practolol and oxprenolol have less cardiac and bronchial side effects than propranolol. They can therefore be used in some of these patients with asthma or heart failure who do not tolerate propranolol and for whom in the United States

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propranolol is specifically contraindicated." [25] Some patients might be better served by the unavailable drugs than by the available ones.

(4) The attempt to measure the overall cost of tighter safety regulations is simply unacceptable: "The difficulty we have with Peltzman's analysis is that we do not know how to put a dollar value on a human life. . . . I do not know what dollar value to put on a child born without arms or legs. . . . That is why it is so difficult to argue with economists. . . ." [26] One could, of course, avoid using dollar values and balance the physical harm from the use of drugs against the physical harm that results from delay and failure to develop drugs. But since the FDA denied that regulation had kept any valuable drug off the U.S. market, it saw no point to this accounting scheme either.

(5) In spite of the preceding argument, the FDA ventured a cost-benefit conclusion: "The allegation has been made that the cost to our society to prevent a thalidomide-type tragedy far exceeds the benefits of a regulatory system developed to prevent such a tragedy. We disagree. We believe that benefits which accrue to society because of our regulatory system are worth the cost and far outweigh any risks." [27] But the FDA did not attempt to justify this conclusion by actually measuring the costs and benefits.

The FDA, in short, used the hearings to enter a sweeping defense of both the regulatory structure and the agency's practices, paying scant attention to the details of Peltzman's analysis and not much more to questions of pharmacology (since the then-existing statements of the drug-lag argument did not themselves present much pharmacological argument). If Peltzman's critique raised important questions, they were left unresolved at the conclusion of the FDA testimony.

Peltzman's critique got more attention on the final day of the hearings. Two economists raised some technical questions about his analysis, but the main event was the rather hostile interrogation of Peltzman by Senator Nelson and the subcommittee staff. Two points were made time and time again. First, noting that Peltzman's analysis depends upon estimates of market demand for various drugs, questioners contended that marketplace tests were inappropriate: what counts, they insisted, is expert judgment. One exchange captures much of the flavor of the dispute:

> Senator NELSON. Well, do I understand correctly, what you are saying is that the marketplace demand determines the scientific value of a product?
>
> Mr. PELTZMAN. No, but turn that around, Senator. If the drug has scientific merit, if it is truly a significant advance as some of these statements say, somebody ought to be buying it. They ought to be buying it more than the average drug.[28]

Senator Nelson then cited one drug which, according to most experts, is prescribed frequently when it should hardly be used at all, and he implied that the therapeutic choices of the typical doctor should not be taken as indicating the worth of drugs.

This view of the average quality of prescribing decisions in the United States may well be central to the position of those who support the 1962 amendments. If doctors generally prescribe poorly, the appropriate governmental response might be to approve drugs with great hesitancy, not because the drugs are unsafe or ineffective when used properly, but rather because they are likely to be used improperly. As one congressional staff assistant told me, "Putting a new drug on the market is putting another weapon in their hands, another killer drug in the hands of doctors who will misuse it." This is a peculiar defense of the 1962 amendments and the FDA, for it implies that the need is less to control drugs and drug companies than to control the practice of medicine—which the present regulatory structure is not well designed to do.

The other central point in Peltzman's exchange with the subcommittee was Peltzman's failure to list specific drugs available in other countries but not in the United States. To no avail Peltzman pointed out, first, that he was not a pharmacologist and, second, that his analysis did not require such a list because it depended as much upon drugs never developed because of the amendments as upon drugs available abroad but not here. Though he mentioned practolol and oxprenolol and cited Wardell's unpublished work, he was repeatedly attacked:

> Senator NELSON. I say to you name one, just one significant drug entity [available

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in Great Britain but not in the United States].

Mr. PELTZMAN. Now, Senator, you know I am not going to do that. I told you—

Senator NELSON. Well, then you have no case at all, do you?

. . . So what I am saying is that your whole case just collapses unless you can prove that we are being deprived of valuable drugs. And if we are not being deprived of valuable drugs, I must say with all due respect, your study is totally useless.[29]

The Nelson hearings, then, can be seen as a hard-line defense of the FDA and of a policy that significant congressional actors had embraced. Serious criticisms of the agency and its policy were not so much refuted as dismissed out of hand.

Reactions to Wardell. Wardell added something new to the debate, an answer to the pharmacological and therapeutic questions which had been used in the subcommittee's attempt to discredit Peltzman. Peltzman could be dismissed as irrelevant because his intellectual framework was foreign to the policy community (as one high FDA official said, "an economic analysis is kind of ridiculous"). His and others' previous drug-lag arguments lacked detailed specifications. However, Wardell provided evidence within a framework the FDA could accept (thus, the same high FDA official called Wardell's work "important"). There is reason to think that arguments of the kind Wardell advanced and facts such as those he presented have had an impact at the FDA.

While the FDA's decision-making process tries to involve many individuals in decisions on new drugs, there are points in the process where single individuals can block approvals. According to several members of the FDA staff, there had been one individual with such power over cardiovascular drugs, a person who was suspicious of anything he was told by the drug companies and who believed that in general there were already enough drugs on the market. ("Both are sound attitudes, but he carried them to extremes.") As a result, between 1968 and 1972, no new cardiovascular drugs were approved. Then FDA management became convinced that there was in fact a lag, at least in cardiovascular drugs. Begining in 1970 it took steps to remove what it saw as bottlenecks in the drug approval process. In September 1974, Wardell testified before two subcommittees chaired by Senator Kennedy that the situation had improved: "I have been critical of the FDA in the past but I must acknowledge that in the last 2½ years the FDA has improved markedly. Large anachronisms still remain, which I pointed out 2 or 3 years ago. But I have found they are decreasing in most areas and in some cases have vanished. . . ." [30]

. . . Growing dissatisfaction with the results of the new drug approval process led the FDA to recognize it had a problem. . . . In response, it improved the process and continued to support the basic outlines of the policy. Why the policy itself is to be supported remains obscure.

Dr. Richard Crout, director of the FDA's Bureau of Drugs, appeared with Wardell and retracted previous FDA statements on the drug lag. Senator Kennedy reminded the witnesses that an FDA official had told the Nelson subcommittee that "there is no condition amenable to drug therapy which cannot be treated as effectively in the United States as anywhere in the world and that the American public is not being deprived of safe and efficacious drugs." Dr. Crout replied that "we would modify that statement today. . . ." He explained that in the list of drugs available elsewhere but not in the United States, "you can pick out drugs . . . that we recognize are potential gains from the standpoint of somewhat improved effectiveness, improved safety and convenience gains." He later pointed directly to the cause of the drug lag: "it is evident that regulatory requirements are an important influence on the availability of new drugs in this or any other country, and any drug lag that exists in this country regarding important drugs is an inevitable result of the standards set by our laws on safety and effectiveness." He rejected, however, suggestions that the 1962 amendments be repealed.[31]

It is difficult to reconcile such statements with earlier FDA testimony. Presumably what happened is that growing dissatisfaction with

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the results of the new drug approval process led the FDA to recognize it had a problem. (Personnel changes in top management speeded this recognition.) In response, it improved the process and continued to support the basic outlines of the policy. Why the policy itself is to be supported remains obscure.

In any event, Wardell's analysis, or something similar to it, appears to have contributed to a modest reorganization within the FDA. Congress showed no great enthusiasm for Wardell and gave the reorganization a very chilly reception. What from one perspective looked like a reorganization of the agency for the purpose of better serving the public interest appeared from another perspective to be a purge of those who were protecting the public from the drug industry. Such a pressure model interpretation was suggested by associates of Ralph Nader in 1972:

> In the past three weeks, an acute and deepening crisis has developed at the Food and Drug Administration which seriously threatens the health of American citizens. Two medical doctors, John Nestor and John Winkler, both specialists in cardiovascular disease with unassailable records of protecting the public from harmful drugs, have been removed from their positions and assigned new tasks.
>
> ...By these adverse actions against two doctors who have served the public in an exemplary way, FDA officials are supporting fears that they are more responsive to complaints from industry than to their responsibility to protect the public health.[32]

The reorganization led to the approval of certain drugs. Subsequently, in 1974, procedures used by the FDA in reaching these approvals were attacked in hearings before a subcommittee of the House Committee on Government Operations, and the matter of the purges was aired in hearings before two of Senator Kennedy's subcommittees. A Morton Mintz story in the *Washington Post* captures the sense of the hearings: "Eleven Food and Drug Administration scientists charged yesterday that the FDA's top echelon always supports them when they recommend approval of new medicines for the market but commonly harasses and intimidates them when they question the safety or effectiveness of new drugs." The FDA responded with a 900-page report which, not surprisingly, concluded that on the whole the charges were without foundation and that the agency was neither improperly subject to industry influences nor biased towards approval of drugs.[33] Caspar Weinberger, then secretary of the Department of Health, Education, and Welfare, appointed a Review Panel on New Drug Regulation to look into the charges and the FDA's investigation of its actions. The panel's first report (1976) concluded, in a mere 524 pages, that the FDA's investigation was inadequate and advised David Mathews, HEW's new head, that some of the charges should be reinvestigated.

Reluctant at first to authorize a new investigation, Secretary of HEW David Mathews later did so, and the 700-page report of that investigation was released in April 1977.[34] Findings were mixed. There was indeed a purge at the FDA (the report uses more neutral terminology), and improper (in some cases unlawful) methods were used to carry it out and cover up what had been done. The aim of the purge was to "neutralize" some medical officers who took an "adversarial" stance toward the drug industry in reviewing NDAs. There were also improper contacts with the drug industry. However, the purge did not result from these relatively infrequent improper contacts, and the FDA was not dominated by the drug industry. Rather, top FDA officials appointed during the Nixon administration independently believed that an extreme adversarial position was inappropriate and that drug approval should be facilitated. In other words, while the results were those predicted by the pressure model, they came about for different reasons. The report makes it exquisitely clear that policy changed at the FDA, but it does not say whether the change was desirable or undesirable. The panel is also considering the substance of drug approval decisions, but its conclusions have yet to be released.

In summary, Wardell's approach to evaluation was received far more sympathetically at the FDA than was Peltzman's, which called for a way of looking at the world radically different from that normally found at the FDA. But politicians and officials who view the world in pressure terms saw the FDA's efforts to shorten the drug lag as capitulation to industry. There is little or no evidence, for example, that mem-

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bers of Congress were moved greatly by Wardell's arguments. Indeed, in a strict sense there is little evidence that Wardell influenced the FDA either. It is possible that FDA officials responded not to Wardell, but rather to industry pressures—or to their own views, as the review panel suggests—concerning the drugs Wardell considered significant. I cannot resolve this question, except by saying that the FDA treated Wardell's critique as if it were important.

Conclusions

Conclusions drawn from a case study apply only to that single case. Nevertheless I offer several generalizations—hypotheses—here. I think they make sense in light of the material in this article, but I make no greater claim for them.

On Congress and Policy Analysis. Hypothesis: Congress is almost totally impervious to systematic policy analysis, particularly in the short run.

It is possible to examine the Peltzman and Wardell analyses carefully and then reject the conclusions because of shortcomings in the analyses. But on Capitol Hill the rejection had nothing to do with careful examination. Several reasons, taken together, suggest an explanation for this.

(1) Members of Congress and staffers involved with drug regulation have substantial investments in at least the general outlines of current policy and practice. They have staked out positions as defenders of the "public interest" against the drug manufacturers, positions that are useful in generating political support and needed publicity. To have bought the conclusions of Peltzman and Wardell would have required reversing positions and liquidating investments, not politically attractive steps. In general, policy analysis is more likely to be dangerous than helpful to politicians because it often finds flaws in programs that they and their constituents support.

In this context, careful consideration of analysis becomes wasteful: the sensible response to unwelcome conclusions is to ignore them as long as possible and then try to discredit them. Such was the fate of Peltzman. As for Wardell, once the FDA came to agree with some of the particulars of his analysis, a new strategy was required: congressional attention turned from the substance of policy to the FDA "purge." This brought good publicity, and the difficult policy questions could be ignored.

(2) The dominant mode of analysis on Capitol Hill, the pressure group model, is uncongenial to policy analysis based on other models. Seemingly locked into their own approach, members of Congress and staffers respond to evaluations based on other approaches by placing them within the pressure model. Policy analysis is seen as merely the continuation of pressure politics by other means, another weapon to be used to support predetermined positions. What counts is not whether an analysis is technically competent, or even correct, but which side it supports. In his study of how congressmen decide how to vote, John Kingdon said: "When asked . . . how he sorted out the conflicting scientific claims, one congressman snorted: 'We don't. That's ridiculous. You have a general position. Once you assume that posture, you use the scientists' testimony as ammunition. The idea that a guy starts with a clean slate and weighs the evidence is absurd.' " [35]

For many congressmen, to accept Wardell's or Peltzman's conclusions would be to cave in under pressure from the drug manufacturers. Senator Nelson gave Peltzman's testimony roughly the same reception that F. Lee Bailey gave the testimony of Dr. Joel Fort in the Patty Hearst trial, and for much the same reason: it was for the wrong side. FDA actions producing results suggested by Wardell's analysis were viewed by Congress entirely in terms of the pressure model. (As noted above, that model can lead in a different direction, but supporters of that side of the model do not generally surface in Congress.)

. . . There appears to be a congressional bias towards specific and visible victims, and against unknown and unidentifiable (perhaps merely hypothetical) ones. . . . The implication of this is that the political system—and Congress in particular—will be inefficient in the saving of lives. In some situations, this will lead to overprotection. . . .

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(3) Two risks are inherent in drug regulation, the risk of harm from approved drugs and the risk of the consequences of delay in marketing new drugs (or of failing to develop them at all). In a sense, these risks are symmetrical. As economist Stanley Lebergott told the Nelson subcommittee in its 1973 hearings, "the central point is, you are choosing one set of deaths and suffering and illness and cost against another. That is the only choice open to us." [36] In another sense, however, the risks are not symmetrical. On the one side, therapeutic accidents often produce identifiable victims. Horrible pictures can be shown; grieving families can testify; particular decisions can be blamed. On the other side, the victims are not so easily identified, and their injuries are not so easily traceable to particular decisions and causes. While policy analysis may weight the two sides equally, congressmen do not. Rather, there appears to be a congressional bias towards specific and visible victims, and against unknown and unidentifiable (perhaps merely hypothetical) ones.

This bias is surely not limited to Congress. It appears whenever we must balance "statistical lives" against the lives of identifiable individuals: we spend almost unlimited amounts to rescue a trapped miner, but comparatively little per life saved for improvements in mine safety. But congressmen, oriented as they are towards distributive benefits, may be particularly susceptible to this bias: diffuse benefits have something of the character of public goods, for which it is hard to claim credit. The implication of this is that the political system—and Congress in particular—will be inefficient in the saving of lives. In some situations, this will lead to overprotection in consumer protection legislation. Of course, as the mine safety example suggests, the bias may also lead to underprotection when unidentifiable victims predominate.

On the FDA and Policy Analysis. Hypothesis: The FDA is less impervious to systematic analysis of policy results than is Congress because its ways of thinking are more congenial to such analysis than is the congressional way of thinking.

FDA officials reacted to Peltzman much as congressmen did: they rejected his entire approach out of hand, finding its economic framework so foreign to their modes of analysis that they felt no call to take it seriously. Wardell, however, approached the problem in precisely the terms normally used within the FDA in deciding on drug approval: what is the evidence of effectiveness, and how safe is the drug? The FDA appears to have accepted much of what Wardell said about particular decisions, but to have translated his critique of the regulatory structure into more congenial terms, a critique of process within the structure. In a sense, then, the FDA reacted to Wardell just as Congress did: it placed his analysis within its own models and treated it only in those terms. But on the FDA's terms, Wardell had something to say.

On the Potential Impact of Policy Analysis. Hypothesis: the potential impact of comprehensive, systematic analysis of the effects of policy is limited.

If an analysis does not produce results consistent with the needs, preconceptions, and perspectives of policy-makers, it is likely to be ignored—even attacked. Indeed, because no analysis is perfect and complete, "even those who would like to see more analysis in policy making will not wholly endorse it, will never wholly accept its results, and will obviously want some kind of political machinery to make policy decisions. . . ." [37]

This limited role for analysis may be entirely appropriate. Peltzman's work is interesting, but the framework of his analysis is open to question, and even within that framework his results may be subject to dispute—with the dispute being, of necessity, highly technical. The point is not whether Peltzman is right or wrong, but that a congressional committee could hardly hope to resolve the technical issues involved; if it could, the resolution might not be the correct one. One economist on the staff of HEW's review panel concluded, perhaps correctly, "that it is impossible on

If an analysis does not produce results consistent with the needs, preconceptions, and perspectives of policy-makers, it is likely to be ignored—even attacked.

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the available evidence to draw firm judgments about the amendments' overall impact on consumer welfare." [38] Under the circumstances, what can the policy-maker do? The congressman can take the side of his traditional allies, which is precisely what Senators Nelson and Kennedy did. The bureaucrat can say he is just doing his job, which is what the officials at the FDA did. Politics is one mechanism for evaluating evidence. It may even be an adequate one.

On Pharmaceutical Regulation. Some of the critics and some of the defenders of the 1962 amendments share an interest in how drugs are actually used by doctors. This is not surprising. Because the present system of regulation is a blunt instrument that either blocks a drug from almost all use or makes it available to all doctors to use as they please, it will always be possible to show both that useful drugs are not available (when they presumably should be) and that patients are being injured in appalling numbers by drugs already approved. This suggests that perhaps something should be done about the way doctors prescribe drugs.

Proposals to accomplish this abound. Wardell suggests greater reliance on postmarketing surveillance for evidence concerning safety and efficiency, combined with additional controls on drug utilization. "If the initial release of new drugs were restricted to individuals or institutions with special facilities to monitor them, drugs could be released at a considerably earlier stage than at present." [39] He also would permit the therapeutic use of drugs still in investigational status. Finally, he gives consideration to systems of control which would allow use of certain drugs by some doctors but not by others.

Richard Merrill, now FDA's general counsel, proposes alterations in the rules governing malpractice suits against doctors (and in the rules governing suits against drug manufacturers) so as to more tightly control the use of drugs.[40] The effect would be to turn drug descriptions and labels—which the FDA must approve—into a set of rules controlling how drugs may be used.

Senators Kennedy and Javits have proposed legislation which would, among other things, create a new stage in the regulation of some drugs (S. 2697, 94th Congress). Once safety had been reasonably established, a drug would be placed on a "conditional release" status for the purpose of obtaining information about effectiveness and other matters. During the period of conditional release, doctors not approved by the government would not be allowed to use the drug, and approved doctors would not be allowed to use the drug for unapproved purposes. Congressman Paul Rogers has proposed a different kind of controlled release (H.R. 1603, 95th Congress). While neither bill would do much to regulate the use of drugs that are already on the market, both would provide some kind of control over the use of new drugs by the medical profession.

Whether any of these proposals will become law is uncertain. Given the intent to control aspects of the practice of medicine, the opposition of the organized medical profession seems guaranteed. In any event, agreement on controlling the use of new drugs masks underlying disagreement on balancing the risks and benefits of these new drugs. Senator Javits said of his proposal that it "seeks to respond to the problem of 'drug-lag,' but at the same time protect the public health." [41] I suspect that it would not fully accomplish this. Rather, it would shift the controversy to somewhat different decisions in the regulatory process. That process would still require a risk-benefit calculus and, as this essay has argued, consensus on the results of that calculus is not easily reached.

PHARMACEUTICAL regulation takes place in a world of uncertain and incomplete information. It touches upon fundamental values and attitudes and profoundly affects the lives of nearly all of us—and the fortunes of some. The power of analysis to resolve such highly charged conflict is, as we have seen, limited. Political decisions are made politically, with the analysts on the sidelines.

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Notes

[1] This statement, like others in this paper, is from interviews I conducted with various officials in Washington. While not all interviewees wished to remain anonymous, all quotations from them will be anonymous here.

[2] F. J. Ingelfinger, "The Side Effects of Aspirin," *New England Journal of Medicine*, November 1974, p. 1197.

[3] Milton Silverman, prepared testimony before U.S. Congress, Senate, Select Committee on Small Business, Subcommittee on Monopoly, May 26, 1976.

[4] U.S. Congress, House, Committee on Government Operations, *Hearings on Drug Safety*, Part 1, 88th Congress, 2d session–89th Congress, 2d session (1964), p. 185.

[5] Morton Mintz, *By Prescription Only* (Boston: Beacon Press, 1967), pp. 260-61.

[6] 21 United States Code §355 (d).

[7] If a drug is intended for long-term use, showing that it is safe for such use may take decades. FDA has therefore devised a sort of half-way house—rarely used—for important drugs of this kind.

[8] Milton Silverman and Philip R. Lee, *Pills, Profits, and Politics* (Berkeley: University of California Press, 1974), p. 119.

[9] *Hearings on Drug Safety*, Part 1, p. 224.

[10] There is one major exception. FDA controls apply to each use of the drug claimed by the manufacturer. If a drug is approved for one purpose, doctors may use it for another, though the manufacturer neither claims this use nor provides suitable directions, cautions, and the like. The absence of claims and information may discourage doctors from using a drug in this way, but there is little evidence on this point.

[11] William M. Wardell and Louis Lasagna, *Regulation and Drug Development* (Washington, D.C.: American Enterprise Institute, 1975), p. 63.

[12] Sam Peltzman, "The Benefits and Costs of New Drug Regulation," in Richard L. Landau, ed., *Regulating New Drugs* (Chicago: University of Chicago Center for Policy Study, 1973), pp. 113-211; "An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments," *Journal of Political Economy*, September-October 1973, pp. 1049-91; *Regulation of Pharmaceutical Innovation* (Washington, D.C.: American Enterprise Institute, 1974).

[13] William M. Wardell, "Developments in the Introduction of New Drugs in the United States and Britain, 1971-74," in Robert B. Helms, ed., *Drug Development and Marketing* (Washington, D.C.: American Enterprise Institute, 1975), pp. 165-81. Earlier papers by Wardell are reviewed and updated in Wardell and Lasagna, *Regulation and Drug Development*.

[14] Wardell, "Therapeutic Implications of the Drug Lag," *Clinical Pharmacology and Therapeutics*, January 1974, p. 90.

[15] U.S. Congress, Senate, Committee on Labor and Public Welfare and Committee on the Judiciary, *Hearings on Regulation of New Drug R. & D. by the Food and Drug Administration*, 93d Congress, 2d session (1974), p. 466.

[16] Ibid., p. 207.

[17] Ibid. There is reason to think that at least one drug, L-dopa, was approved for marketing in part because of congressional interest (Joseph D. Cooper, "Purpose, Technique, and Strategy in the Regulation of New Drugs," in Landau, ed., *Regulating New Drugs*, pp. 21-32).

[18] Richard J. Crout, "New Drug Regulation and Its Impact on Innovation," in Samuel A. Mitchell and Emery A. Link, eds., *Impact of Public Policy on Drug Innovation and Pricing* (Washington, D.C.: American University, 1976), p. 243.

[19] Joseph D. Cooper, *Philosophy and Technology of Drug Assessment* (Washington, D.C.: Interdisciplinary Communications Associates, 1971), vol. 2, *The Quality of Advice*, pp. 8-9.

[20] U.S. Congress, Senate, Select Committee on Small Business, *Hearings on Competitive Problems in the Drug Industry*, Part 23 *(Development and Marketing of Prescription Drugs)*, 93d Congress, 1st session (1973), p. 9107.

[21] Ibid., p. 9387.

[22] Peltzman, *Regulation of Pharmaceutical Innovation*, p. 86.

[23] *Hearings on Competitive Problems in the Drug Industry*, p. 9377.

[24] Ibid., p. 9382.

[25] Wardell and Lasagna, *Regulation and Drug Development*, p. 62; citations to the medical literature, here omitted, show this information was available several years before the hearings. Other side effects became known after introduction of these drugs in Britain.

[26] *Hearings on Competitive Problems in the Drug Industry*, p. 9383.

[27] Ibid., p. 9367.

[28] Ibid., p. 9820.

[29] Ibid., pp. 9834-35.

[30] *Hearings on Regulation of New Drug R. & D. by the Food and Drug Administration*, p. 490.

[31] Ibid., pp. 477 and 505.

[32] Sidney Wolfe and Anita Johnson, "Conflict against the Public Interest at the Bureau of Drugs," in Alexander M. Schmidt, *The Commissioner's Report of Investigation of Charges* (Washington, D.C.: Food and Drug Administration, 1975), pp. 242-51.

[33] Schmidt, *The Commissioner's Report of Investigation of Charges*, pp. 895-96.

[34] Department of Health, Education, and Welfare, Review Panel on New Drug Regulation, *Investigations of Allegations Relating to the Bureau of Drugs, Food and Drug Administration*, a report to the Review Panel on New Drug Regulation by Its Special Counsel and His Staff, April 1977.

[35] John W. Kingdon, *Congressmen's Voting Decisions* (New York: Harper and Row, 1973), p. 223.

[36] *Hearings on Competitive Problems in the Drug Industry*, p. 9859.

[37] Charles E. Lindblom, *The Policy-Making Process* (Englewood Cliffs, N.J.: Prentice-Hall, 1968), p. 20.

[38] Charles F. Stone, "Economic Effect of New Drug Regulation in the United States," prepared for the Review Panel on New Drug Regulation, November 1976.

[39] Wardell and Lasagna, *Regulation and Drug Development*, p. 147.

[40] Richard A. Merrill, "Compensation for Prescription Drug Injuries," *Virginia Law Review*, January 1973, pp. 1-120.

[41] *Congressional Record*, November 20, 1975, p. S 70512.

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The Judicialization of Standardless Rulemaking

Two Wrongs Make a Right

Antonin Scalia

THE subject of the present article is administrative procedure. By definition, procedure does not deal with the substance of controversial issues; and by nature, it is an arcane, bloodless, and thus unattractive subject of study—for legislators no less than for the readers of *Regulation*. For these reasons, as all wise lawyers know, a change in governing procedures is the simplest way to effect a basic change in the end product (that is, the substance) of governmental action.

This article is prompted by, though it is not really about, that aspect of the *Home Box Office* decision (noted on pages 4–5, this issue) which deals with administrative procedure. That holding finds ex parte contacts to be unlawful in agency rulemaking, which means that all discussions of the issues between persons outside the agency (including members of Congress) and agency heads and staff will henceforth have to be "on the record" and with notice to other participants in the proceeding. It is, in my opinion, quite likely that the Supreme Court will reverse the holding, since it is—in respects which it is beside the point to pursue here—sharply out of accord with governing statutory provisions and their legislative history. Right or wrong, however, the decision represents a trend, on the part not merely of the courts but of the Congress and the executive branch as well. That trend is likely to continue unabated. My interest here is in considering briefly its effects upon the character of federal administration.

The trend I refer to is what might aptly be termed the progressive judicialization of the rulemaking process. To perceive the phenomenon, one must understand the basic procedural structure which was established in 1947 by the Administrative Procedure Act (APA), and which is still the generally applicable framework for administrative action. This consists of a formal procedure and an informal procedure. The former, applicable primarily to the category of agency action known as adjudication, is based upon the common-law judicial model: it presumes adverse parties litigating a relatively particularized factual issue. Since one of those adverse parties may be (and usually is) the agency staff itself, seeking, for example, to impose a sanction for alleged violation of law or of agency regulations, the formal procedure includes a "separation-of-functions" provision, which rigidly separates the litigating portion of the agency from the decision-making portion. At the initial stage, the proceeding is conducted and the decision made by an administrative law judge whose tenure and compensation are not under the agency's control. Like a common-law trial, the formal APA procedure confers a right to present oral evidence and to conduct reasonable cross-examination of witnesses; the transcript of this proceeding, along with all documents filed, "constitutes the exclusive record for decision"; and the courts

Antonin Scalia is a professor of law at the University of Chicago and an adjunct scholar of the American Enterprise Institute. He has served in the federal government as assistant attorney general, Office of Legal Counsel, as chairman of the Administrative Conference of the United States, and as general counsel of the Office of Telecommunications Policy.

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must reverse an agency decision "unsupported by substantial evidence" in this record.

In contrast to this judicialized procedure, there is a prescribed informal procedure that is used for virtually all agency rulemaking. This is the "notice-and-comment" procedure, under which the proposed rules developed by the agency staff are published in the *Federal Register* and written public comments invited. As a discretionary matter most agencies frequently hold public hearings on rules of major impact, but such hearings typically resemble a congressional committee hearing rather than a common-law trial. They need not be chaired by an administrative law judge; witnesses are not subject to cross-examination by adverse parties; and the committee staff which drafted the proposed rules, and which may appear to explain and defend them, is not subsequently excluded from advising on the final question of whether the rules should be adopted. When judicial review is sought, and in the absence of any contrary statutory provision, the applicable standard is not whether the rules are "supported by substantial evidence," but whether they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."

As the legislative history of the APA shows, the formal and informal procedures described above were primarily meant to govern, respectively, the "judicial" and "legislative" aspects of agency action.

> The bill provides quite different procedures for the "legislative" and "judicial" functions of administrative agencies. [Senate Report No. 752, 79th Congress, 1st session, 1945.]
>
> First, there are the legislative functions of administrative agencies, where they issue general or particular regulations which in form or effect are like the statutes of the Congress. . . . Congress—if it had the time, the staff, and the organization—might itself prescribe these things. Because Congress does not do so itself and yet desires that these things be done, the legislative power to do them has been conferred upon administrative officers or agencies.
>
> The second kind of administrative operation is found in those familiar situations in which an officer or agency determines the particular case just as, in other fields of law, the courts determine cases. . . . What the agencies do in these cases is to determine, just as a court might determine, the liability of a party or the redress to which a party is entitled in a specific case on a specific state of facts and under stated law. [Statement of Rep. Francis E. Walter, member of House Judiciary Committee, *Congressional Record*, May 24, 1946, pp. H 5647-5655.]

What has developed since the enactment of the APA—and with an accelerating pace in recent years—is a progressive conversion of the informal procedure to the formal, an assimilation of the legislative model to the judicial.

This development was to some extent inevitable because of the central position occupied by the courts as the forum for reviewing not only adjudication but rulemaking as well. The judicial procedures are those with which the courts are most familiar and in which they repose the greatest confidence. Moreover, court review is cumbersome and inefficient (if not totally ineffective) when superimposed upon a decisional process that is not specifically designed, as is the judicial model, to facilitate such review by placing all of the relevant material upon a "record." Thus, the courts have imposed upon the rulemaking process procedural requirements well beyond what was originally envisioned. They have mandated such significant procedural steps as the publication of information in the agency's possession relevant to the proposed rules, a detailed statement of the agency's reasoning and its factual basis, explicit response to all major contentions raised by participants in the rulemaking proceeding, in some cases cross-examination of expert witnesses, and most recently—if the *Home Box Office* decision is upheld—abstention from ex parte contacts. Moreover, the APA standard for court reversal of agency rulemaking ("arbitrary, capricious or an abuse of discretion") has been applied in such a way that many informed observers consider it indistinguishable from what was meant to be the more stringent "substantial evidence" test applicable to adjudication.

It is, however, not only the courts that have been responsible for the progressive judicialization of the rulemaking process. The Congress, in making new delegations of rulemaking authority, has repeatedly departed from the scheme of the APA, invariably in the direc-

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tion of assimilating rulemaking to APA formal adjudication. Oral proceedings (though without cross-examination) are often required; the provision of a "substantial evidence" review standard for particular rulemaking has become commonplace; and in very recent enactments the Congress has even defined a "record" for rulemaking purposes. The executive agencies themselves have also contributed to the formalization of the process. As the court noted in *Home Box Office*, for example, the FCC had criticized the practice of ex parte contacts and had suggested that it might impose some constraints against them.

With the foregoing as painful but necessary prologue, let me come at last to my point, which is the effect of these procedural developments upon the nature and the product of federal administration. I take it to be axiomatic that, in a democratic government, agency rulemaking is meant to reflect the will of the elected assembly. This goal can intelligently be pursued in one of two ways. First, the delegation of legislative, rulemaking authority may be made with such precise instructions concerning the end to be achieved that logic and technological competence (which are qualities reviewable by the courts) will dictate a relatively narrow range of results. Or, second, the manner of exercising an imprecise delegation may be designed to reflect the same forces that work upon the legislature itself, and thus to produce approximately the same results.

Until the 1930s the federal government had, formally at least, chosen the first of these courses. "Congress," said the Supreme Court (and seemed to mean it), "cannot delegate any part of its legislative power except under the limitation of a prescribed standard." This was the principle of unconstitutional delegation of legislative authority—which, if it was ever really followed, has in any case not been applied since 1935. Modern delegations include standards no more precise (and no more limiting) than the injunction to adopt rules "in the public interest." The system has functioned reasonably well, however, because—either consciously or through that instinctive capacity for fashioning workable arrangements that characterizes Anglo-American politics—the second method for achieving rough compliance with the legislative will has in fact been adopted.

It is unquestionably true that the regulated industries have had—to use the censorious phrase adopted by the *Home Box Office* case—"undue" influence in the rulemaking decisions of their governing agencies. The court might have added that Ralph Nader, Common Cause, and the Sierra Club have also had "undue" influence—in the sense that their positions, like those of the proximately affected industries, have been given greater weight than positions espoused by, let us say, private citizens such as you and me. The rulemaking process has assuredly not been an open forum producing an ultimate decision which values each presentation on the basis of its intrinsic intellectual worth, with no regard to the *political power* of its proponent. To be sure, the initial stage of agency action has consisted of inquiries and investigations designed to elicit all the facts and to disclose, where possible, the most rational solution; but the final rules have been undeniably political—not (hopefully) in the partisan sense, but in the sense that the sometimes irrational desires of the public and of interest groups within the public have affected the outcome. This would be grave criticism of a court, but is it so clear that it is proper ground for censure of the agencies? Is it so clear that it produces a result that contradicts, rather than parallels, the result that would obtain in that best of all possible worlds, where the legislature itself does all the rulemaking? I suggest that the answer is quite clearly no. If the views of the airlines (and of the Airline Passengers Association) are given greater weight by the CAB than the views of John Doe, one would expect them to be given "undue" weight by the Congress as well, with respect to legislation vitally affecting their selfish interests. This process of accommodating public desires, including the ardent support or vehement opposition of interest groups most proximately affected, is an essential part of the democratic process, however untidy and unanalytic it may be. To prohibit rulemaking agencies from seeking such accommodation, and at the same time to give those agencies no more specific legislative charge than to act "in the public interest," is to convert a large segment of our legal system into a technocracy. It may indeed be true that the present system of what I might term "politically sensitive" agency rulemaking does not mirror, or mimic, congressional action with

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sufficient accuracy; in my view congressional specification of intelligible and enforceable standards to be applied in the rules is a much more effective means of ensuring compliance with the popular will. But where such standards to guide the agency have not been imposed, the existing system seems infinitely preferable to the regime of "public policy by analysis" which the *Home Box Office* court evidently favors.

The reference to that case recalls me to the subject of procedure. Procedure is not imposed for its own sake, but rather because of its tendency to give greatest effect to those factors that are important in the decision-making process and to exclude those factors that are irrelevant. The imposition of judicial procedures and the application of a "substantial evidence," adjudication-type standard of review spring from a perception that rulemaking is essentially and perhaps exclusively an analytic and rational process, in which the "best" result is reached through collection and examination of all relevant facts by skilled officials aided in their deliberations by the arguments of interested persons. Such procedural developments are, in other words, in principle a repudiation of politically sensitive rulemaking—and in effect may be its destruction. An agency will be operating politically blind if it is not permitted to have frank and informal discussions with members of Congress and the vitally concerned interest groups; and it will often be unable to fashion a politically acceptable (and therefore enduring) resolution of regulatory problems without some process of negotiation off the record. A politically sensitive agency, moreover, may be able to demonstrate that its rules are not "arbitrary, capricious or an abuse of discretion," but can hardly be expected to meet a strict "substantial evidence" standard of review when the evidence is *not* the only applicable criterion.

As noted above, the procedural innovations that embody the ideal of depoliticized agency rulemaking have captured the imagination not only of the courts but of the Congress and (perhaps) the agencies as well. I do not mean to criticize that ideal, except when it is conjoined with an absence of specific, legislatively imposed standards. Institutional arrangements have a way of finding their own accommodation, however, and it will be no surprise if the continued judicialization of rulemaking procedures automatically produces a dramatic reduction of "standardless" rulemaking. This may occur in part because the Congress, seeing the failure of the judicialized process to approximate the results that Congress itself would produce, and finding itself constantly under pressure to reverse agency action at the instance of the constituencies whose "undue" influence at the agency stage has been eliminated, will simply decline to make or continue delegations of imprecise character. More likely still, the reduction may occur because the agencies themselves will refrain from entering into authorized "standardless" rulemaking whose political consequences they are prevented from taking into account. After all, the principal reason agencies give weight to political realities under the present system is that the penalty for failure to do so is punishment of the incumbent party at the polls, or more immediately, an embarrassing reversal of agency decisions through legislation, along with congressional retribution upon agency programs and appropriated funds. When, because of newly imposed procedures, the risk of these consequences cannot be assessed and cannot be taken into account in the final decision, the agencies will be inclined to seek safety in inaction—or will send legislative proposals to Congress instead of issuing definitive rules.

Hence my ambivalence toward the developments I have described. While an agency "legislating" under a political check is better than an agency "legislating" under no democratically imposed constraints at all, surely it is best for the Congress itself to determine the main lines of legislation—and to do so in detail much greater than the platitudinous goals of pursuing "the public interest" or preventing "sex discrimination." The judicialization of rulemaking, which seems to me generally prompted by motives which mistake the character of the rulemaking process in the present statutory context, is likely to compel a change in that context. We may be witnessing, under the guise of procedural reform, the return to a system of more limited congressional delegation. To that extent, out of evil cometh good—or out of a vaguely moralistic tinkering which misperceives the nature of existing processes, an accidentally better system for giving the people greater control.

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Readings
of particular interest

In Defense of Price Cutting

"A Theory of Competition" by G. Warren Nutter and John H. Moore, in *Journal of Law and Economics*, April 1976.

What makes firms compete? Crucial though this question may be to the regulation of competition among firms, Warren Nutter and John Moore of the University of Virginia suggest that it has been avoided by economists.

In that branch of economics that specializes in the study of industries, the emphasis is not on the competitive process but on "structure"—the organization of industry. Data are gathered and tests run to see whether industrial concentration (usually, the fraction of industry sales accounted for by the four or eight largest firms) correlates with certain measures of industrial performance (excessive profit rates, the price-cost margin). All of this is done without knowing just what it is that the data should be expected to reveal. Performance is supposed to improve with decreases in concentration because, so the argument goes, it just makes sense to assume that an increase in the number of firms sharing a market will cause prices to fall.

The difficulty, as Nutter and Moore show, is that the competitive process is not so simple after all. There is, to begin with, no "frictionless" tendency for managements to begin cutting price after the firms sharing a market reach some magic number. Some managements will cut price, despite the long-run disadvantages to their firms of doing so, because they believe that others will not cut prices, at least not for a while. The temporary gain may outweigh the permanent loss. Competition is therefore not merely a numbers game in which a particular index of concentration translates smoothly into a particular index of performance, without any disturbances along the way. Wherever competition is at work, some firms will charge lower prices than other firms. Indeed, it is the fact of price cutting—not some idealized state of affairs in which "many" firms charge the same "competitive" price—that distinguishes competition from monopoly.

Managers know that the success of a price cut depends on the alertness of their customers and their rivals, and they know that different buyers and sellers will engage in different amounts of "search" for low prices. At a given cost of search, buyers will engage in more search the longer they expect a given seller to wait before he matches a rival's suspected price cut and the less search in which they expect sellers to engage. Similarly, sellers will search more intensively the more they expect their "representative" buyers to search and the fewer the number of firms in the industry.

This line of reasoning yields some counterintuitive results. The authors discover, for example, that a rise in the number of firms may not increase the temporary gain from a price cut even though it will reduce the permanent loss. While "the number of firms" does therefore have "a great deal to do with making price cheaper," the behavioral effects of changes in concentration are not nearly so simple as traditional industrial organization theory has assumed. First, the number of firms required to generate competition differs from one industry to another and, second, the discriminatory practices now outlawed by antitrust legislation may have merit when they are weighed against the desirability of competition. "Since friction is necessary to generate competition, one should be cautious about condemning such practices as price discrimination or 'secret' price-cutting out of hand. They may do more good than harm, as we judge such things."

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Trends in Regulation

"The New 'Social Regulation'" by William Lilley III and James C. Miller III in *The Public Interest*, Spring 1977; AEI Reprint No. 66.

William Lilley of the House Budget Committee and James Miller of the American Enterprise Institute begin by noting a sharp rise in all types of government regulation in the 1970–75 period, the major part of it occurring not in economic regulation but in the newer category of social regulation (see table). According to the authors, both former officials of the Council on Wage and Price Stability, these two categories of regulation employ fundamentally different approaches. Economic regulation usually applies to the rates and services of a given industry (for example, airlines or trucking), whereas social regulation specifies, often in minute detail, the product that must result and the conditions under which it must be produced (for example, toys incorporating certain specifications or dust-free factories). Also, social regulation, which applies across the board, affects far more consumers than does old-style economic regulation.

The authors believe that, particularly in the case of social regulation, the country pays far too much for what it is getting. They ascribe this to two factors, the general regulatory approach and, more important, the performance of the regulatory agencies. First, the process often gets off to a bad start because of the regulatory approach selected. Typically, that choice is based upon inadequate information and characterized by an unwillingness to weigh the costs of various methods and a resistance to considering alternatives. Some of this, the authors note, must be blamed on legislators rather than regulators. Congress often mandates a single approach to a regulatory problem—and sometimes only a single standard for evaluating benefits under that approach.

But, second, agency performance in the post-selection phase almost guarantees a poor result. Officials and staff of regulatory agencies tend to have a philosophical attraction to regulation—to the idea that government can produce a better outcome than people left to their own devices. They are then placed in an environment where evenhandedness seems to require generally punitive standards applied to everyone, rather than differentiated standards applied according to the costs and benefits of the specific situation. Also they are conditioned to expect their most serious political trouble from proponents of the regulatory approach and make an effort to avoid trouble from that quarter by fashioning detailed regulations, far more extensive than the problem or the prevailing information might justify.

INDICES OF GROWTH IN FEDERAL REGULATION, 1970–1975
(dollars in millions)

Year	Major "Economic" Regulatory Agencies		Major "Social" Regulatory Agencies		Number of Pages	
	Number	Expenditures	Number	Expenditures	*Federal Register*	*Code of Federal Regulations*
1970	8	$166	12	$1,449	20,036	54,105
1971	8	$197	14	$1,882	25,447	54,487
1972	8	$246	14	$2,248	28,924	61,035
1973	8	$199	17	$2,774	35,592	64,852
1974	9	$304	17	$3,860	42,422	69,270
1975	10	$428	17	$4,251	60,221	72,200
Percent increase 1970–75	25	157	42	193	201	33

Source: *The Public Interest.*

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More on Rate-of-Return Regulation

"A Note on the Optimal Investment Policy of the Regulated Firm" by David Peterson and James Vander Weide, in *Atlantic Economic Journal*, Fall 1976.

This contribution by Professors Peterson and Vander Weide of Duke University further enriches the work begun by Harvey Averch and L. L. Johnson's seminal analysis of regulation. Averch and Johnson, whose findings have intrigued economists and provided ammunition for consumer groups, asked how regulation of a firm's rate of return would affect that firm's investment policies. The Peterson/Vander Weide article extends the analysis by looking at investment decisions over time.

Averch and Johnson's principal conclusion was that regulated firms overinvest in plant and equipment compared to unregulated firms. Their analysis begins by postulating two firms, each producing a single good using only two inputs, labor and capital, and each able to draw upon unlimited quantities of these inputs at constant unit prices and to readily substitute one for the other. The only difference between the two firms is that one is regulated in such a way that it can earn no more than a "fair" rate of return on its capital investment.

The conclusion that regulated firms overinvest in physical capital makes intuitive sense. If a firm is guaranteed a fixed rate of return on its capital investment, as most utilities are, one would expect that firm to invest as much as possible. This overinvestment pushes the firm's cost of production above what it would be without regulation. Put another way, it is a regulation-induced inefficiency.

In order to derive their results mathematically, Averch and Johnson make a number of assumptions that differ markedly from conditions in the real world. Nevertheless, consumer advocates have seized upon their results to argue—in electric utility rate hearings and elsewhere—that this or that utility deliberately overinvests in plant and equipment in order to increase its rate base, and thereby its rates.

The importance of the Peterson/Vander Weide article is its finding that, under more realistic assumptions, the tendency for rate-of-return regulation to induce overinvestment does not always hold. In fact, they find cases where a regulated firm may actually underinvest in capital.

Regulatory Illusion

"Inflation, Regulation, and Utility Stock Prices" by Michael W. Keran, in *Bell Journal of Economics*, Spring 1976.

Investors gloating over their high dividends on utility stocks should take a closer look. For, according to Michael Keran of the Federal Reserve Bank of San Francisco, those stocks they expect to behave like stocks are acting more like bonds.

Using statistical analysis, researcher Keran demonstrates that, in periods of inflation, investor expectations force regulated industries to increase current yield in compensation for declining real rates of return. The problem is that the regulatory authorities generally set prices so that a utility earns a fixed nominal rate on the book value of its capital stock. As inflation picks up speed the real value of this rate declines. True, the regulators allow price increases based on higher costs—and even on higher interest costs associated with new bond issues. But so far they have disallowed increases in the return on book-value equity. Thus, in effect, utility stocks have become fixed income securities.

The author argues that regulators behave as if they had "money illusion," but unfortunately the markets do not. As inflation accelerated after 1965, utility dividends climbed in a pattern mimicking bond interest, whereas utility stock prices remained relatively flat, losing ground when compared to their unregulated cousins. Thus the regulators have caused losses for utility stockholders relative to nonregulated industrial stockholders.

High yields are, of course, attractive to investors seeking relatively fixed income. However, through various expansions of the basic formula R (rate) $= Y$ (yield) $+ g$ (expected growth), Keran demonstrates how poorly protected those yields may be.

As inflation persists, utilities face increasing costs of capital, almost as if they were financing their operations only with debt. The

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result may be fewer resources allocated to utilities, and therefore fewer utility services available to consumers, than would otherwise be the case. Keran concludes with a warning from P. L. Joskow and Paul MacAvoy: "Without substantial increases in the rate of return on equity allowed by regulatory commissions, it is unlikely that sufficient capital can be raised to achieve historic growth rates in capacity."

Management Self-Indulgence

"Managerial Objectives in Regulated Industries: Expense Preference Behavior in Banking" by Franklin R. Edwards, in *Journal of Political Economy*, February 1977.

Profit-maximizing firms occupy hallowed ground in the realm of traditional economic theory. But in the world of regulated industries, their place is not so secure. In this world, expense preference rather than profit maximization may be the firm's principal goal, says Franklin Edwards of Columbia University.

"Expense preference behavior" is a rather inelegant phrase which means simply that firms do not try to earn as much profit as possible. Instead, managers appropriate some potential profits for their own enjoyment by hiring larger staffs and by giving themselves higher salaries and more emoluments than they would if they did try to maximize profits.

From an examination of banking-industry data for forty-four metropolitan areas, Edwards finds that as competition falls, labor expenses tend to rise. This is inconsistent with the hypotheses of profit maximization, which would have predicted that less competition would raise profits but leave the demand for labor unchanged. It is consistent, however, with the hypothesis that managers indulge themselves with larger staffs and higher salaries in the face of weaker competition.

The fact that banking is a highly regulated industry is an important element in the finding that expense preference behavior may better describe the goals of the firm than does profit maximization. For expense preference to be possible, two conditions must be satisfied. First, ownership of the firm must be separated from control of the firm. This separation, in conjunction with the "transactions costs" that the owners (that is, stockholders) must incur to put the reins on management, gives management the leeway it needs to practice expense preference behavior.

The second condition is that there be market imperfections in the industry. In the banking industry there are a number of such imperfections: key interest rates are regulated, entry into the industry and into specific markets is limited, and branching and mergers are strictly controlled. All of these "imperfections" are the result of regulation. This suggests the possibility—a possibility that Edwards recognizes—that not only banking but also most other regulated industries may behave in accordance with expense preference theory.

A Major Theoretical Advance

"Toward a More General Theory of Regulation" by Sam Peltzman, in *Journal of Law and Economics*, August 1976; AEI Reprint No. 71.

Sam Peltzman of the University of Chicago asks: is the public interest served by regulation? High purpose is always expressed as the intent, both in setting up a regulatory program and in making a regulatory decision. However, skepticism about whether high purpose is actually achieved in practice is widespread. Many maintain that in contrast to its constructive—or at least benign—intent, regulation serves special interests. Observers ranging from Ralph Nader to George Stigler have argued that regulation frequently serves mainly the interest of the regulated.

In this provocative article, Peltzman develops a framework for analyzing regulatory behavior that builds upon an idea introduced by Stigler—that regulation is a way of enlisting state power in pursuit of private goals.

Peltzman's approach recognizes that most regulatory proceedings involve a number of groups each trying to advance its own interests. In making decisions, regulators must take into account both the interests of these groups and the strength with which they are pursued, an essentially political undertaking

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that can be analyzed *as if* vote-getting considerations were directly impinging on the regulatory process. The pursuit of the private goals sought through regulation usually takes the form of struggles over rate-setting, service requirements, conditions of entry, and the like. While these struggles are the means by which private advantage is pursued, they can be viewed *as if* redistribution of income or wealth were the primary thrust of the regulatory decision-making process.

The framework that Peltzman develops based on these two propositions can be used to examine the effects of a wide range of conditions upon regulatory behavior. Peltzman examines the implications of differences in conditions influencing the ability to assemble effective coalitions, differences in costs and industry structure, and changes in political or economic variables. A surprising number of implications that can be tested empirically are generated by this analytic framework.

Although considerable technical knowledge is required to follow the details of Peltzman's argument, the basic ideas underlying his approach and many of the implications derived from it are quite easily grasped. For example, the "capture theory" (essentially the idea that regulation serves the interests of the industry subject to regulation) turns out to be one possible result. Other implications involve the structure of regulated prices and sharing by different interest groups of the transfers associated with regulation.

Advertising and Concentrated Industries

"Advertising, Concentration, and Price-Cost Margins" by Allyn D. Strickland and Leonard W. Weiss, in *Journal of Political Economy*, October 1976; *Industrial Concentration and Advertising Intensity* by Stanley I. Ornstein, American Enterprise Institute for Public Policy Research, 1977.

The idea that industrial concentration and advertising are related in some harmful way dates back at least to the late forties when Nicholas Kaldor argued that advertising-created scale economies and brand loyalties cause industrial concentration. Although the evidence for Kaldor's argument is at best mixed, the idea that advertising creates "shared monopoly" and "barriers to entry" has been the basis for a number of antitrust complaints, notably the cereals case currently before the Federal Trade Commission. Two recent studies—one by Leonard Weiss of the University of Wisconsin and Allyn Strickland of the University of Delaware and the other by Stanley Ornstein of UCLA—offer some improvements over earlier statistical tests without reducing the scope for disagreement over Kaldor's argument.

Both studies employ large samples of narrowly defined (four-digit Census of Manufactures) industries, and both draw their advertising-to-sales data from the U.S. input-output tables. Ornstein reports findings for 1947, 1963, and 1967. Strickland and Weiss report findings only for 1963 but increase the explanatory power of their tests by incorporating not only industrial concentration and advertising intensity, but also certain other variables, including the price-cost margin and a proxy for production economies of scale.

The principal difference in the two studies lies in their findings about the strength and direction of the advertising-concentration relationship. Ornstein argues that, on theoretical grounds, it is concentration that may cause advertising intensity to rise, rather than the other way around. His findings indicate a positive and significant—but weak—relationship: advertising tends to rise with concentration, but concentration ordinarily explains no more than 10 percent of the variation in advertising. Strickland and Weiss, on the other hand, find that initially concentration rises with advertising and subsequently advertising falls with concentration (a "quadratic" or inverted-U relationship). Advertising intensity and production economies of scale explain over 60 percent of the variation in industrial concentration in their sample of consumer goods industries.

Despite these conflicting results, neither study supports the brand-loyalty hypothesis. Noting that advertising does not significantly affect price-cost margins for consumer goods, Strickland and Weiss conclude "that the product differentiation barrier to entry is not very great."

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Contradiction on Capitol Hill

"The Crusade against Federal Paper Work" by Paul H. Weaver, in *Fortune*, November 1976.

Though resentment continues to grow against the amount of paperwork required by the federal government of all segments of society, Paul H. Weaver of *Fortune* finds there are inherent limitations to improving the situation. The biggest category of government paperwork consists of forms people fill out for their own advantage—forms that often return significant benefits such as reliable statistics. The redundancy of state and federal forms is a problem that defies solution as long as we have a federalist system, and duplication within federal paperwork cannot be eliminated because nearly identical forms often have different functions. For instance, Census Bureau surveys must preserve confidentiality, while a similar form of the Federal Trade Commission gathers information for purposes of publication or legal prosecution.

However, the author maintains that something can and should be done about the excessive paperwork imposed by certain kinds of laws passed in the last decade. These deal with equal opportunity, energy, environmental problems, occupational safety, and retirement plans. The Employment Retirement Income Security Act, for instance, has hurt the very workers it is designed to protect. Partly because of the paperwork burden imposed by the act, there has been a significant decrease in the number of pension plans run by small employers.

Such excessive paperwork is symptomatic of a larger problem rooted in a certain hostile attitude on the part of legislators and a tendency on their part to impose standards without fully considering the consequences. The Ford administration saw the danger of using reports as a mechanism of law enforcement, but Congress continues to pursue policies that mandate paperwork even while it stages a dramatic crusade against it through the Commission on Federal Paperwork. Basic reforms thus do not seem possible; the one hope is that people in and out of government will continue to make modest marginal reforms within the limits of their authority.

Bigger Government—Less Control?

"Can Government Regulate Itself?" by James Q. Wilson and Patricia Rachal, in *The Public Interest*, Winter 1977.

The growth of central government raises basic questions about the ability of one government agency to modify the behavior of another. Harvard Professor James Wilson and Patricia Rachal, a graduate student, suggest that although such centralization means that the various public bureaucracies must increasingly give orders to each other, their ability to do so effectively is inherently limited. Even within the same level of government, an agency will have great difficulty in attaining its goal if, to do so, it must change the behavior of another agency. Generally, it is easier for a public agency to change the behavior of a private organization than that of another public agency.

For example, they point out that the Veterans Administration is less susceptible than private hospitals to reform efforts by other governmental agencies; the Environmental Protection Agency can influence private utility companies more easily than it can the Tennessee Valley Authority; the Boston Inspection Department has much greater success correcting complaints against private landlords than against the Boston Housing Authority; and the Office of Federal Contracts Compliance is ineffective in getting other agencies to impose affirmative action policies on private contractors.

The inefficacy of attempts at interagency control has various causes. It is difficult for civil servants to affect the behavior of personnel in other agencies, especially those of higher rank. A federal agency can have considerable financial influence over a private firm, but it has no direct control over the personnel, structure, or budget of another agency. Furthermore, courts do not, except in unusual circumstances, mediate interagency conflicts, because this can result in a violation of the constitutional principle of separation of powers doctrine.

Thus, the nationalization of enterprises reduces the chances that those enterprises will be effectively regulated. "It may be," the authors conclude, "that as power in a society be-

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comes more concentrated, it becomes less effective in serving a variety of public goals."

A Dead End?

"The Reformation of American Administrative Law" by Richard Stewart, in *Harvard Law Review*, June 1975.

Administrative law, that part of the law concerned with the procedures of regulatory agencies, is undergoing a fundamental change that calls into question its proper role in our legal system. The most salient feature of this change, says Richard Stewart of Harvard Law School, is the increasing importance of public interest groups in administrative decision-making. Published two years ago, Stewart's 144-page article remains the most thoughtful and comprehensive work on the origins and implications of this development. His conclusions offer little hope to those seeking to improve the content of regulatory decisions and the process by which they are made.

The central task of administrative law in America has been to check the discretionary power of regulatory agencies in a way that reconciles the control exercised over private citizens by unelected officials with the traditions of American democracy. The traditional view saw the agency as a mere transmission belt for legislative directives. The Congress passed a law; the agency applied the policy expressed in the law, following procedures designed to ensure that it did so accurately and rationally; and the courts, limited to providing judicial review, decided whether the agency had strayed beyond the law.

Something happened to this model. Severely strained by New Deal legislation delegating wide administrative discretion to new agencies created to solve a variety of problems, it was partially rescued as the courts put certain controls on the exercise of that discretion. Later, the problems Congress sought to solve through regulation became more complex and less amenable to resolution by administrative decision, and experience withered the faith that professional administrators can reliably carry out legislative mandates in pursuit of an objective "public interest."

Today, the exercise of agency power is no longer viewed as a way of transmitting legislative decisions into specific policy. Instead, Stewart argues, judges, legislators, administrators, and lawyers see agencies as essentially engaged in a legislative process—one of adjusting the competing claims of various private interests affected by agency policy. Each agency is an arena where the regulators, the regulated, and the groups likely to be affected by a decision struggle to work their will.

As this view of the agency decision-making process gained ascendency, regulation-watchers from across the political spectrum reached a consensus on the quality of agency decisions —it has been poor. The reason for this, many believe, is that the agencies are responding to the organized interests before them, at the cost of neglecting other, perhaps broader, interests. At its crudest, this explanation sees the agencies as captives of the enterprises they are regulating.

When one combines this explanation for poor agency performance with the view that the regulatory process is like the workings of a legislature, it is easy to see why there has been a trend towards involving more groups in agency deliberations. If the Federal Communications Commission does not adequately represent the interests of television viewers in license renewal proceedings, then allow ad hoc groups of viewers to intervene.

This interest-group representation model is helpful, Stewart argues, if it is indeed true that better and fairer decisions result from greater participation. But is this the case? How can we be sure that all the appropriate interests will be listened to? Does not this model, by complicating the issues and increasing the number of contending views, expand the opportunities for arbitrary decision-making? Moreover, the interest group model imposes substantial costs upon society in terms of delay and other transaction costs. Are these costs worth the benefits?

Administrative law appears headed for a dead end. The old model of agency decision-making has been largely replaced but the usefulness of the new model for solving the pressing problem of agency discretion is doubtful at best. However, for lack of a better solution, it is likely to continue to dominate.

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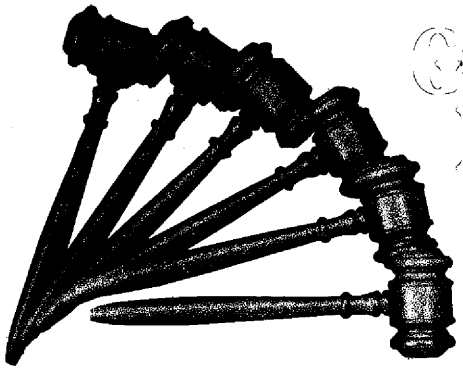

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